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(पहला पुनरीक्षण)

Indian Standard

EXPLANATORY GUIDE ON IS/ISO 9001 : 2000

(First Revision)

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FOREWORD

This Special Publication (First Revisoin) was adopted by the Bureau of Indian Standards, after the draft finalized by the Quality Management Sectional Committee had been approved by the Management and Systems Division Council.

IS/ISO 9000 family of standards were initially published in year 1987 and later revised in year 1994. With a view to help Indian industry in understanding the requirements of IS/ISO 9001 : 1994 'Explanatory guide for application of quality system standards (IS/ISO 9001, IS/ISO 9002 and IS/ISO 9003)' was published in 1997 as SP 63 : 1997. Thereafter, Bureau of Indian Standards brought out Special Publication on 'Handbook on IS/ISO 9000 for small businesses' as SP 65 : 1998, by adopting ISO Handbook on the subject.

With the publication of revised ISO 9000 family of standards in 2000 and their adoption by BIS in toto as IS/ISO 9000 standards, a need was felt to revise SP 63 : 1997 and SP 65 : 1998 so that the Indian industry can understand the various concepts and implement quality management systems as per IS/ISO 9000 : 2000 family of standards. It was further decided that only one Special Publication on 'Explanatory Guide to IS/ISO 9001 : 2000' would be published by revising SP 63 : 1997 and SP 65 : 1998 would be withdrawn, as revised SP 63 would be applicable to all types and sizes of organizations.

This Special Publication is only for guidance, which explains the requirements of IS/ISO 9001 : 2000 and how these may be implemented. It does not set any new or additional requirements, or otherwise change the requirements of IS/ISO 9001 : 2000.

In this Special Publication, the full text of each clause of IS/ISO 9001 : 2000 is documented first in box, followed by the relevant guidance with regards to its application along with examples, wherever required.

The guidance should be read in conjunction with the clause of IS/ISO 9001 : 2000 since in cases where the text of the clause is clear, only limited advice is rendered.

It may be mentioned that wherever the word 'product' is appearing in this Special Publication, it will include both 'product and/or service'.

INTRODUCTION TO QUALITY MANAGEMENT SYSTEMS

What is a Quality Management System?

All organizations, large and small, have an established way or system of doing business. A quality management system is the way an organization directs and controls its business activities associated with establishment of its policy and objectives for quality and then achieving these objectives.

Quality management system is about identification of various processes (activities), why and how these are performed and documenting those processes, which are necessary for effective operation of the system. Further, as objective evidence, some records have also to be established and maintained.

Since quality management system is about how an organization is managed, it can be applied to all types and sizes of organizations and to all aspects of management, such as, marketing, purchase, production, service provision, stores, human resource, training and finance. It is up to the organization to decide the extent of its applicability.

Quality management system standards are not alternate to product and/or service standards. In fact, they are complementary to each other. Quality management system helps an organization to build in systems so that it is able to provide quality products and/or services consistently. However, 'quality' of the product and/or service is defined in the product and/or service standards. Therefore, use of product and/or service standards together with quality management system standards help in maintaining and improving quality of the products and/or services, which result in enhancing customers' satisfaction and competitiveness of the business.

A quality management system, on its own, will not necessarily lead to an improvement of work processes or product or service quality. It would not solve all the problems. It is a means to take a more systematic approach to the business objectives. One should aim to improve one's profit to justify the investment needed to implement and maintain the quality management system.

Quality management system should not result in excessive bureaucracy or paperwork or lack of flexibility. All organizations already have a structure and this should be the basis on which the quality management system is to be built. It may be found that an organization is already carrying out many of the requirements included in IS/ISO 9001 but may have not stated how they are done.

What is IS/ISO 9000 Family of Standards on Quality Management System?

IS/ISO 9000 family of standards consists of following four standards:

a) IS/ISO 9000 : 2000, which sets out the concepts, principles, fundamentals and vocabulary for quality management systems;
b) IS/ISO 9001 : 2000, which sets out quality management system requirements, which have to be met and demonstrated by an organization. Therefore, quality system certification can be granted against this standard;
c) IS/ISO 9004 : 2000, which provides guidance for continual improvement of an organization's overall performance. As it is a guidance standard, certification can not be granted against this standard; and
d) IS/ISO 19011 : 2002, which provides guidelines on auditing quality management system (as well as environmental management system).

Why to Have Quality Management System?

Implementation of effective quality management system:

a) provides confidence to the customers that the organization is capable of meeting their requirements on consistent basis;
b) improves organization performance and productivity;
c) maintains and continually improves quality of the products and/or services to meet customers' requirements and implied needs;
d) provides role clarity within the organization as the responsibilities and authorities are well laid down in the system, which may result in having cordial atmosphere within the organization;
e) not only helps in maintaining market share, but also opens new market opportunities as an organization is now able to compete on the same basis as larger organizations (for example, ability to tender or submit price quotation);
f) provides evidence to customers and potential customers of what an organization can do for them, thereby enhancing customer satisfaction; and
g) improves image of the organization through IS/ISO 9001 certification.

How to Implement Quality Management System?

This Special Publication is written for people who wish to put a quality management system in place. The first step necessary in establishment of quality management system is the commitment and involvement of top management. If the top management is not committed, then there is no use of going ahead for establishing this system. The next step is to use this Special Publication so as to understand what a quality management system is and what are its requirements as given in IS/ISO 9001.

It is not the purpose of IS/ISO 9001 to impose a total new way of managing the business. One should integrate IS/ISO 9001 into its existing business practice. This Special Publication will help in identifying what IS/ISO 9001 requires and how these requirements relate to activities of the organization. This comparison should identify the areas requiring further development of quality management system. Probably many of the requirements are already being met or perhaps partially met. For example, when placing job advertisements for personnel, the job descriptions are written down. Before placing an order with one of suppliers, one already has some idea of that supplier's capability. When an instruction is written on how some activity is to be carried out, a work instruction is being created. Similar other examples are of the quality plan or a checklist.

Having determined how the requirements of IS/ISO 9001 apply to an organization, the next step is to look at the activities and record what is actually being done.

It has to be seen which requirements of IS/ISO 9001, an organization has already been meeting and those it is not yet meeting. Further, ask customers if they have any particular requirements that might need to be considered for inclusion in the quality management system. It is important to realize that there should be no reason to substantially change the way the business is run.

After doing this gap analysis and knowing the quantum of work, it has to be decided as to how much can be done within the organization? This depends upon availability of competent personnel, time and other resources. This will determine whether external assistance is required and if yes, to what extent and in which areas?

If external assistance is required, one should be careful while choosing off-the-shelf solutions that cannot be adequately adapted to the organization, whether these are offered in computer package or by a consultant. For selection of a competent consultant, guidance can be taken from IS/ISO 10019 : 2005 'Guidelines for the selection of quality management system consultant and use of their services'.

For the gaps identified, it has to be determined whether, documentation is compulsory as per requirements of IS/ISO 9001, for example, documentation of "Quality policy", "Procedures on corrective action", "Preventive action", "Document control", etc. This Special Publication will help in this regard. If some documentation is required, fix the responsibility. It is important that all people in the organization are involved in this process and not fix the responsibility of an individual to carry out all jobs. Further, ask the relevant people to write down what their jobs cover and how they carry out them.

Collate this in sequences relevant to the list of main business activities made earlier. Ensure that documentation as per the requirements of IS/ISO 9001 and also that necessary for effective operation of the business practice are established.

Keep the quality management system simple and functional (that is relevant to organization's operations).

Consider the feedback information from the quality management system through internal audits (*see* **8.2.2**) and use it to improving the systems.

For further step-by-step methodology in this regard, *see* Annex A.

Why Sometimes Objectives of Quality System are not Achieved?

The two main causes which lead to failure in achieving the objectives of quality management system are:

a) Noninvolvement of the top management due to lack of will, time or resources; and
b) Non-active participation of people either due to ineffective or gap of communication or lack of sufficient motivation.

What Does ISO 9001 Certification Mean?

After establishing effective quality management system in an organization, it may be demonstrated to the customers or potential customers or for enhancing the image of the organization and business. A decision regarding certification may also be influenced by the competitors or by regulatory or statutory requirements. For this, an organization may go for IS/ISO 9001 certification. Certification is regarded as the formal recognition by others of the quality management system.

If the above option is being considered, then the first step is to contact the certification bodies, like Bureau of Indian Standards to find out what is offered, what the likely costs are, the period for which the certification will apply, and how frequently they will want to look at the quality management system. Some certification bodies may also be offering an initial pre-assessment to assess for the readiness for the certification. This can be of major benefit in finding out what needs to be done.

GUIDANCE ON IS/ISO 9001

INTRODUCTION

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design implementation of an organization's quality management system is influenced by varying needs, particular objectives, the product provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for product. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

The International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

What Does it Mean?

For guidance please see "Introduction to quality management system" as given in the beginning of IS/ISO 9001.

IS/ISO 9001 is based on the following eight quality management principles:

a) *Customer focus*

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) *Leadership*

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) *Involvement of people*

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

d) *Process approach*

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) *System approach to management*

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

f) *Continual improvement*

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) *Factual approach to decision-making*

Effective decisions are based on the analysis of data and information.

h) *Mutually beneficial supplier relationships*

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Successful use of the eight quality management principles by an organization will result in benefits to all interest parties, such as improved monetary returns, its creation of value and increased stability.

For further guidance on quality management principles, reference may be made to ISO document 'Eight quality management principles', available free of cost on ISO/TC 176 website.

0.2 Process Approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the on-going control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,
b) the need to consider processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers playa significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE: In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

Plan:	establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.
Do:	implement the processes.
Check:	monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
Act:	take actions to continually improve process performance.

What Does it Mean?

The conceptual model given in Fig. 1 of IS/ISO 9001 and is important for better understanding of the standard. In IS/ISO 9001 this is referred as a model of a process-based quality management system because it highlights the main processes, namely, Management responsibility; Resource management; Product realization; Measurement, Analysis and Improvement, which are integral to this standard. These processes may already be existing in the organization.

This model is basically customer driven as it is based on the premise that anything and everything to do with quality starts and ends with the customer. In the diagram, the customer is shown on both the left and right side.

The model starts with determining the needs and expectations of the customer. These form the inputs to the quality management system, particularly in planning for product realization and/or service provision processes.

The main process flow that enables the product and/or service to emerge is shown across the lower part of the figure, as Product realization. This box covers the various processes that an organization needs to do to make the product and/or provide the service, which is an output from an organization.

The various processes used in the realization of product and/or service have to be measured/monitored. The

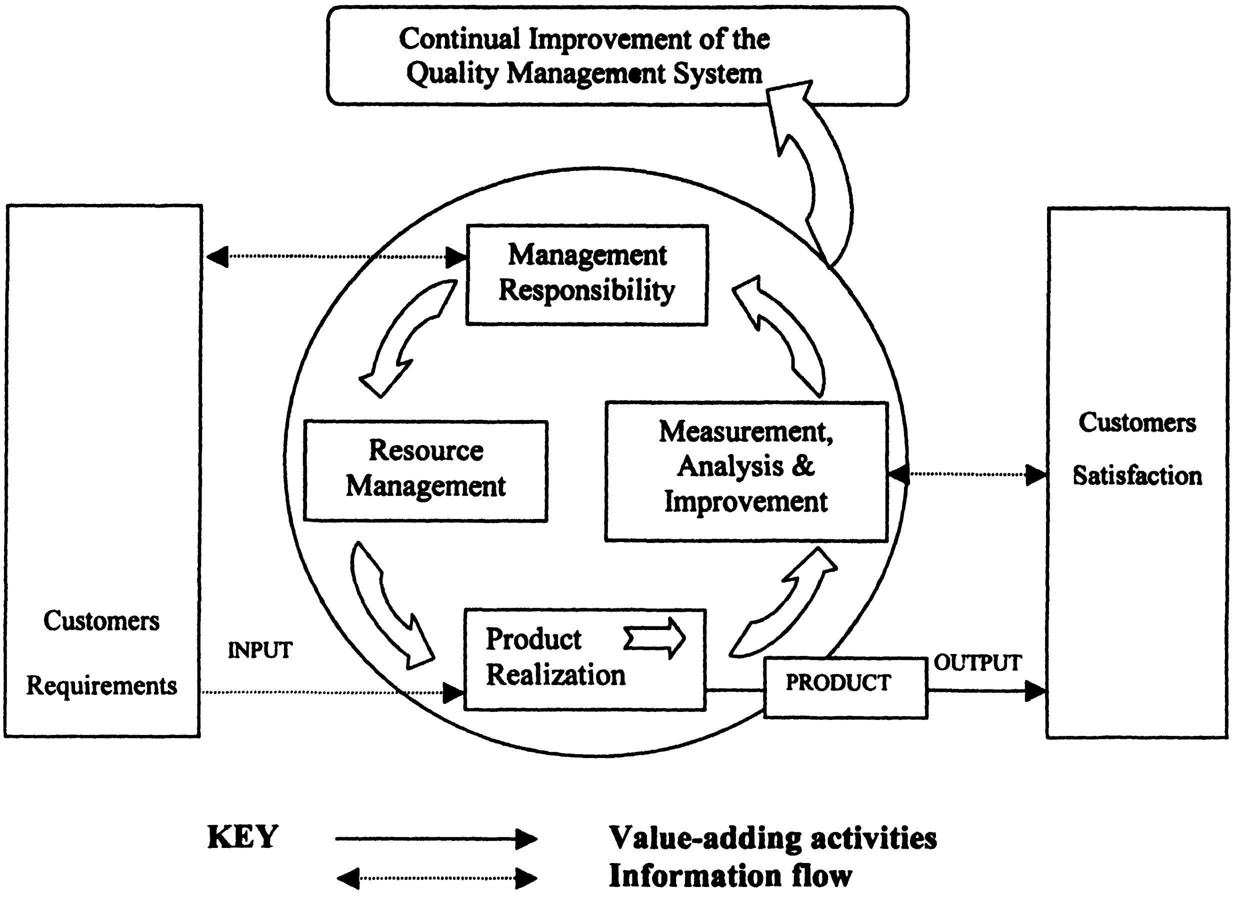


FIG. 1 MODEL OF A PROCESS BASED QUALITY MANAGEMENT SYSTEM

results of these measurements, including those from customer feedback, are to be analyzed so as to identify dominant causes for nonconformities. Not only the nonconformities have to be corrected, but also corrective action have to be taken on the causes of these nonconformities so that in future such nonconformities do not recur. These corrective action, together with preventive action (those actions taken in advance so as to prevent occurrence of nonconformities) would help an organization in continual improvement of quality of its products and/or services. Therefore, there is a separate box shown titled as 'Measurements, analysis and improvement'

The 'Management responsibility' box explains the importance of the leadership role in the quality management system. The top management should identify the critical processes and determine and provide resources.

It also includes the need for top management to set quality policy and quality objectives. Following from these, there is a need for proper planning. Planning includes the identification of the processes, ensuring that they are adequately documented (*see* **4.2.1**). These documents define the way the organization wants to operate its processes. This model further highlights the need for the top management to be customer focused, that is, knowing the customer expectations viz-a-viz the organization's capability to achieve the same. Further, top management need to act on the information and data that show how well or how poorly the system is working, and provide or adjust the resources needed to maintain and improve it.

The 'Resource management' box explains the need for determining and providing adequate resources for developing and implementing the quality management system. Resources include, infrastructure, work environment, materials and human. Organization needs to ensure that people are trained and competent to do the tasks that are assigned of them.

PDCA Cycle

IS/ISO 9001 has adopted PDCA cycle as a tool for continual improvement. It can be observed from Fig. 1 that the boxes for 'Management responsibility' and 'Resource management' constitute the **Plan** function, the box for

'Product realization' constitutes **Do** function, the 'Measurement' portion in the box for 'Measurement, analysis, improvement' constitute the **Check** function and 'Analysis and improvement' portion in the box for 'Measurement, analysis, improvement' constitute the **Act** function. In this manner the quality management system can be continually improved.

For further guidance on Process approach, reference may be made to ISO/TC 176 website.

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

What Does it Mean?

IS/ISO 9001 and IS/ISO 9004 have a common main clause structure, which simplify the use of these two standards in conjunction with each other. IS/ISO 9001 focuses on the customer while IS/ISO 9004 goes beyond to include other interested parties like owners, employees, suppliers, and society. IS/ISO 9001 focuses that an organization should meet the stated requirements of the quality management systems whereas IS/ISO 9004 focuses on meeting the requirements of all the interested parties with minimum resources.

It may be noted that IS/ISO 9004 is a quality management system standard for performance improvement, and is not a guide to the implementation of IS/ISO 9001.

0.4 Compatibility with Other Management Systems

This International Standard has been aligned with ISO 14001 : 1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

What Does it Mean?

Efforts are being made at International level to have one common standard on 'Integrated management system' Further, ISO 14001 : 1996 has been revised to ISO 14001 : 2004 and the same has been adopted by Bureau of Indian Standards in toto as IS/ISO 14001 : 2004.

When reading IS/ISO 9001, note that certain words and phrases have particular significance or meaning. Some explanation of the more important of these is given below:

shall	Whenever this word occurs in IS/ISO 9001, it is used to indicate a requirement that must be fulfilled.
may	These words are used to suggest a course of action. They are never used to indicate a requirement that must be fulfilled.

as appropriate	This word means that one needs to decide how the requirements apply to one's organization, and in some cases they may not.
as necessary or as applicable	These words mean that one need to implement those requirements, which apply to one's organization.

These are to be decided by the organization and not by the auditors in the context in which it is used in the standard. This has to be read with reference to the provisions of the standard.

As the above clauses **0.1**, **0.2**, **0.3** and **0.4** of IS/ISO 9001 provide introduction to quality management system and as such do not contain any requirements; the quality management system cannot be audited against these requirements of this standard.

Indian Standard
EXPLANATORY GUIDE ON IS/ISO 9001 : 2000
(First Revision)

1 SCOPE

1.1 General

This International Standard specifies requirements for a quality management system where an organization:

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

What Does it Mean?

Please note that in this clause emphasis has been laid on two words, namely 'ability' and 'consistently', which is the main purpose of quality management system.

Meeting applicable regulatory requirements means the regulatory requirements for the final product and/or service and not all other regulatory requirements which are not related to product and/or service, for example, factories act, employee related disputes, etc.

For further guidance on customer satisfaction and continual improvement, *see* 3.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

What Does it Mean?

Adherence to the conditions given in this clause is the starting point for conforming to IS/ISO 9001 requirements.

This allows the organization to exclude those requirements given in 7 (and only in 7) which do not apply to an organization (that is one is not doing them, or one is not responsible for them) or may not apply to the products and/or services that they are providing, with the restrictions that by excluding such requirements the product and/or service quality will not be affected.

An organization can not discard a requirement given in 7 as being irrelevant just because it does not want to do it, or because it is not required by regulatory bodies.

When an organization has doubt, whether the requirement is applicable to it or not, it should ask itself:

a) What is the idea or principle behind this requirement?

b) What kind of problem could be prevented by meeting this requirement?

c) Would meeting the requirement give confidence to the customer?

d) If organization is not responsible for the requirement, then who is?

For example, if an organization does not carry out design (7.3), then it does not need any process for design activities.

Other examples where exclusions may apply include:

a) If a measuring equipment is not being used to measure some parameter, then there is no need for calibration requirement as given in 7.6 of IS/ISO 9001.

b) If any property from the customer is not being received for its inclusion in product and/or service, then there is no need to apply requirements of customer property as given in 7.5.4 of IS/ISO 9001.

There may be circumstances where some specific requirements within one of the sub-clauses of 7 may need to be included while the rest of the requirements in that sub-clause could be excluded. For example, in 7.5.3, traceability requirements may be considered for exclusion but not the requirements regarding identification. In that situation, only that particular requirement, which is not applicable, can only be excluded.

However, none of the requirements given in 7 can be excluded which affect the quality of the products and/or services. The exclusions have to be justified in the quality manual (*see* 4.2.2)

2 NORMATIVE REFERENCE

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000 : 2000, Quality management systems — Fundamentals and vocabulary.

The Indian Standards listed in Annex B contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard listed in Annex B.

What Does it Mean?

The reference to IS/ISO 9000 is made to understand fundamentals and vocabulary that is used in the quality management system in IS/ISO 9001 and IS/ISO 9004.

3 TERMS AND DEFINITIONS

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

Supplier ——► Organization ——► Customer

The term "organization" replace the term "supplier" used in ISO 9001 : 1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor"

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

What Does it Mean?

IS/ISO 9001 uses three terms to describe the supply chain as follows:

Organization — your organization, which is developing and implementing the quality management system.

Supplier — your suppliers, that is, those who provide products and/or services to the organization.

Customer — your customers, that is, those who receive products and/or services of the organization.

The above supply chain relationship applies to every organization depending upon the role being played. "Organization" can, at the same time, be the "supplier" of product and/or service to another organization and the "customer" when receiving product and/or service from some other organization.

In IS/ISO 9000 the term "product" is defined so that it includes "service". However, the phrase 'product and/or service' is being used to reinforce the idea that it means product, or services, or both. The term 'product' is used when referring to a physical item. Similarly, 'service' is used when referring to the concept of meeting a customer need that has an intangible component.

Some of the commonly used terms defined in IS/ISO 9000 are reproduced below:

Organization

Group of people or facilities with an arrangement of responsibilities, authorities and relationships.

Top Management

Person or group of people who direct and control an organization.

For example, Chief executive officer, Managing Director, Chairman, Board of Directors, Executive Directors, Partner(s), Single owner.

Process

Set of inter-related or inter-acting activities which transforms inputs into outputs.

NOTES

1 Inputs to a process are generally outputs of other processes.

2 Processes in an organization are generally planned and carried out under controlled conditions to add value.

3 A process where the conformity of the resulting product and/or service can not be readily or economically verified is frequently referred to as a "special process"

Product

Result of a process.

NOTES

1 There are four generic product categories, as follows:

a) service (for example, transport);
b) software (for example, computer programme, dictionary);
c) hardware (for example, engine mechanical part);
d) processed materials (for example, lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or process material depends on the dominant element. For example, the offered product 'automobile' consists of hardware (for example, tyres), processed materials (for example, fuel, cooling liquid), software (for example, engine control software, driver's manual), and service (for example, operating explanations given by the salesman).

2 Service is the result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible. Provision of a service can involve, for example, the following:

a) an activity performed on a customer-supplied tangible product (for example, automobile to be repaired);
b) an activity performed on a customer-supplied intangible product (for example, the income statement needed to prepaid tax return);
c) the delivery of an intangible product (for example, the delivery of information in the context of knowledge transmission);
d) the creation of ambiance for the customer (for example, in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

3 Quality assurance is mainly focused on intended product.

Quality

Degree to which a set of inherent characteristics fulfils requirements.

NOTES

1 The term "quality" can be used with the adjectives such as poor, good or excellent.

2 "Inherent, as opposed to "assigned", means existing in something as a permanent characteristics.

Quality Policy

Overall intentions and direction of an organization related to quality as formally expressed by top management.

NOTES

1 Generally the quality policy is consistent with the overall policy of the organization and provides a framework for setting of quality objectives.

2 Quality management principles presented in this standard can form a basis for the establishment of a quality policy.

Quality Objective

Something sought, or aimed for, related to quality.

NOTES

1 Quality objectives are generally based on the organization's quality policy.

2 Quality objectives are generally specified for relevant functions and levels in the organization.

Quality Management

Coordinated activities to direct and control an organization with regard to quality.

Quality Control

Part of quality management focused on fulfilling quality requirements.

Quality Assurance

Part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality Improvement

Part of quality management focused on increasing the ability to fulfil quality requirements.

NOTE — The requirements can be related to any aspect such as effectiveness, efficiency or traceability.

Management System

System to establish policy and objectives and to achieve those objectives.

NOTE — A management system of an organization can include different management systems, such as a quality management system, a financial management system or an environmental management system.

Quality Management System

Management system to direct and control an organization with regard to quality.

Nonconformity

Non-fulfilment of a requirement.

Example—This term is used to describe any instance of failure to meet a specified requirement. This may be a non-fulfilment of a customer's requirement, a problem with a product and/or a service, a deficiency in the quality management system, or any other situation where what happened was not what was required or expected.

Correction

Action to eliminate a detected nonconformity.

NOTES

1 A correction can be made in conjunction with a corrective action.

2 A correction can be, for example, rework or regrade.

Corrective Action

Action to eliminate the cause of a detected nonconformity or other undesirable situation.

NOTES

1 There can be more than one cause for a nonconformity.

2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

3 There is a distinction between correction and corrective action.

Preventive Action

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Continual Improvement

Recurring activity to increase the ability to fulfil requirements.

NOTE — The process of establishing objectives and finding opportunities for improvement is a continual process through the use of audit findings and audit conclusions, analysis of data, management reviews or other means and generally leads to corrective action or preventive action.

Customer Satisfaction

Customer's perception of the degree to which the customer's requirements have been fulfilled.

NOTES

1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

4 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall:

a) identify the processes needed for the quality management system and their application throughout the organization,
b) determine the sequence and interaction of these processes,
c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitor, measure and analyse these processes, and
f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

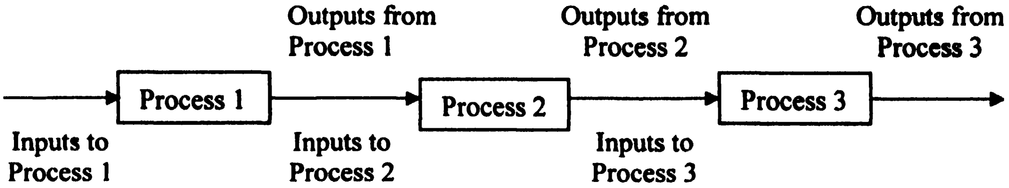
NOTE Processes for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

What Does This Mean?

IS/ISO 9001 promotes the adoption of process approach when developing and implementing quality management systems and emphasizes continual improvement in the quality systems to enhance customer satisfaction by meeting customer requirement. This clause requires that the key processes involved in the organization to be identified and the interaction between these processes needs to be linked up. The processes include not only the product and/or service realization processes, but also those used for management activities for resource management, communication, internal auditing, management review and other processes. The extent to which processes need to be detailed depends on the complexity and stability of the process activities. Simple process activities might require only simple explanations. Complex processes will require detailed explanations to enable understanding of activities and tasks and the inter-relationship to the extent necessary for effective implementation.

The purpose and measurable objective of each process is required to be established and evidence is to be compiled to show its effective control. Process effectiveness can also be assessed by internal or external review processes and focus on continual improvements.

Individual processes rarely occur in isolation. Outputs from one process typically form part of the inputs into subsequent processes as shown below:



The interaction between the organization's processes is to be determined and the networking established. Such processes networking should also include processes which are outsourced and effect quality of product and/or service.

The general requirements of IS/ISO 9001, in fact, stress the importance for an organization to identify, implement, manage and continually improve the effectiveness of the processes that are necessary for the quality management system, and to manage the interactions of these processes in order to achieve the organization's quality policy and objectives.

How to Implement?

Process is defined as "Set of interrelated or inter-acting activities which transform input into output". Inputs and outputs may be tangible or intangible and include equipment, materials, energy, information, human resources, finance etc. To perform activities within the process, appropriate resources have to be allocated. A measurement and monitoring system can be used to compile the information/data and analyze process performance for effecting continual improvements.

As stated in one of the eight quality management principles, on which IS/ISO 9000 standards are based, the process approach ensures that the desired result is achieved more efficiently when activities and resources are managed as a process.

Maintaining and continually improving the process capability can be achieved by applying the PDCA concept at all levels within the organization. This applies equally to high-level strategic processes, such as quality management system planning, or management review, and to simple operational activities carried out as part of product and/or service realization processes.

PDCA is a dynamic cycle that can be deployed within each of the organization processes for continual improvement of both product and/or service realization and other quality management system processes.

Where an organization chooses to outsource a process that affects its ability to provide conforming product and/or service, it has to demonstrate that it exercises sufficient control to ensure that this process is performed to relevant requirements of the organization's quality management system. The controls will depend on the importance of outsourced process, the risk involved and could be in form of:

a) specifications/validation requirement of the process,
b) monitoring/measurement methods, performance targets, and
c) on site inspections, verification and/or audit to be performed by the organization.

Outsourcing is not limited to manufacturing activities but could also include activities in marketing and sales, calibration of equipments, design activities, personnel for after sales service, call centre operation, general maintenance etc.

One of the common methods of grouping the processes is to have a matrix of Business Related Processes, Manufacturing Related Processes and System Related Processes with their interactions.

An example of a typical process for finalizing engineering feasibility report in Engineering Consultancy organization is given in Annex C.

4.2 Documentation Requirements

4.2.1 *General*

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,
c) documented procedures required by this International Standard,
d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
e) records required by this International Standard (see 4.2.4)

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to:

a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

What Does This Mean?

This clause lists the essential requirements of the quality management system which should be documented. Each organization must have a quality policy, which has to be documented. While defining the quality policy, the organization should project its vision, mission and key strategies for the future and the policy should aim at achieving the same. The policy is to be supported by quality objectives which can be short-term or long-term and enable the policy to be achieved.

To facilitate implementation of the quality management system on a continual basis, it has to be documented and this document is called the quality manual. This manual describes all the elements of the quality system applicable to an organization and gives specific details relating to the product and/or service whose quality is being controlled.

How to Implement?

Quality policy should include the intention of the top management of the organization, such as, to become market leader by increasing its market share of the product and/or service being dealt with, to improve the productivity, to excel in quality, to provide maximum satisfaction to the customer on a continual basis and providing training to its employees. Satisfaction of the customer should be one of the primary objectives, keeping in view the expectations and need of other stake holders. It is also important that the commitment of the management is visibly spelt out and the quality policy is issued under the Chief Executives authority. It should be given the wider publicity within the organization and employees made aware of the objectives of the organization and the need for adhering to the quality policy to achieve the stated objectives. Top management needs to review the policy periodically to ensure that it remains pertinent to the business.

The quality objectives support the quality policy and need to be clearly spelt out with specific reference to the activities of the organization. The objective should be SMART that is Specific, measurable, achievable, result oriented and time frame. The quality objectives could be elaborated at the unit/department level clearly bringing out what the quality objectives means to the unit/department activities and what objectives, they should adopt to meet the organization quality objectives. These objectives can be reviewed at periodic intervals to revise the targets set in the objectives, once they are met. On completion or reaching maturity of any particular objective, we can formulate new objectives.

IS/ISO 9001 specifically requires following six procedures to be documented:

Clause No.	**Procedure Required for**
4.2.3	Document control
4.2.4	Control of records
8.2.2	Internal audits
8.3	Control of nonconforming product
8.5.2	Corrective action
8.5.3	Preventive action

The need of additional procedures would basically depend upon the competency of the personnel in the organization and the complexity of the processes and it is for the organization to decide whether to document them or to control the process otherwise.

In addition to the procedures, an organization may require many other documents for effective operation and control of its various processes. Examples of other type of documents may include:

a) Process maps, process flow charts and/or process descriptions;
b) Organization charts;
c) Specifications;
d) Work and/or test instructions;
e) Blank proformae used by various departments for entering data;
f) Documents containing internal communications;
g) Production schedules;
h) Approved supplier lists;
j) Test and inspection plans; and
k) Quality plans.

The documentation should be need based and it should be recognized that excessive documentation does not necessarily give more control of the activity and should be kept to the required minimum. Training can help to reduce the need for detailed documentation, provided that everybody has the information they need to do the job effectively.

IS/ISO 9001 requires minimum 21 records to be maintained, which are as follows:

Clause No.	**Records Required for**
5.6.1	Management reviews
6.2.2 (e)	Education, training, skills and experience
7.1 (d)	Evidence that the realization processes and resulting product and/or service meet requirements.
7.2.2	Results of the review of requirements related to the product and/or service and actions arising from review.
7.3.2	Design and development inputs related to product and/or service requirements.
7.3.4	Results of design and development reviews and any necessary actions.
7.3.5	Results of design and development verification and any necessary actions.
7.3.6	Results of design and development validation and any necessary action.
7.3.7	Results of the review of design and development changes and any necessary actions.
7.4.1	Results of supplies evaluation and any necessary actions arising from the evaluations.
7.5.2 (d)	As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement.
7.5.3	The unique identification of the product and/or service, where traceability is a requirement.
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use.
7.6 (a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist.
7.6	Validity of the previous measuring results when the measuring equipment is found not to conform to requirements.
7.6	Results of calibration and verification of measuring equipment.
8.2.2	Internal audit results and follow-up actions.
8.2.4	Indication of the person(s) authorizing release of product and/or service.
8.3	Nature of the product and/or service nonconformities and any subsequent actions taken, including concessions obtained.
8.5.2	Results of corrective action
8.5.3	Results of preventive action.

The requirement of type of records to be set by the organization depends upon the size of organization, competence of its personnel and the activities performed. The important point is to demonstrate that the processes are in control and data are available for continual improvement rather than just records.

4.2.2 *Quality Manual*

The organization shall establish and maintain a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusions (*see* 1.2),

b) the documented procedure established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

What Does This Mean?

IS/ISO 9001 requires that a quality manual is prepared detailing out the quality management system, its processes and the interaction between the processes. The format and structure of the manual is left to each organization to decide and will depend upon the size, culture and complexity of the organization. The quality manual should include the interaction between the quality processes and also needs to contain or refer to the quality procedures. Procedures may be in a separate document and may be preferable for reasons of keeping the organizations processes confidential. Since IS/ISO 9000 family of standards no longer consists of the three separate models of quality management system and has now uniformly adopted a single standard that is IS/ISO 9001, it is important that the scope should be very clear and any exclusion which the organization has due to its operation are to be highlighted in the Manual.

Let us take the example of an organization which does not have any design activity in the product and/or service provision. The quality manual should then make this a clear exclusion and it will have to demonstrate the basis of the same with full back up. Other example of exclusions could be customer property.

The new standard thereby does not voluntarily allow the organization to decide the scope but goes objectively to allow exclusions only and that too only in 7 of IS/ISO 9001.

The quality manual may be an electronic document provided everyone who needs to use the manual has access to computer, otherwise it could be a loose leaf binder so that it may be changed whenever revisions are issued. Every page needs to be identified and numbered to ensure that the manual is complete and up-to-date.

How to Implement?

Describing the quality management system in the form of a documented quality manual has several uses which can be kept in consideration while formulating the same.

Customers before entering into a partnership, are likely to use the quality manual to help them decide whether they are making the right choice.

Employees, particularly new or potential ones will know about the products and/or services of the organization and get an overview of the procedures and what are their objectives.

Suppliers will find it useful to understand the business and how they can better serve the organization.

Certification body will need it to understand the business to enable them to audit, assess and certify it comprehensively.

Shareholders, lenders or investors may find it useful to truly describe how business is run, much more informative. Competitors will also be very interested to obtain a copy and so the organization should be careful as to what it writes there so that confidential or classified information are not given away.

IS/ISO 9001 does not require all these things of the quality manual, but it is worth considering the possible uses and potential as a marketing tool before deciding its format, presentation and distribution.

Some examples of quality manual are:

a) A small organization may find it appropriate to include the description of its entire quality management system within a single manual, including all the documented procedures required by IS/ISO 9001, and

b) Large multi-national organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

The rest of the quality management system needs to be documented but in how much detail depends on the approach that has been adopted and the competency of the people in the organization. The procedure should describe what, when, where and how a process to be performed and who is responsible. Forms and checklists could be used if supported by objectives and records to substantiate the results of the process.

4.2.3 *Control of Documents*

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

What Does This Mean?

The clause emphasizes that control of documents is a critical activity and great problems are faced during implementing the quality management system in this area. In the beginning, over half of the non-compliances in most of the organizations are in the area of document control.

Documents are to be reviewed and approved before they are issued or changed. There needs to be a mechanism for indicating that the documents have been reviewed, that is putting signatures on the contents page after review. In case of electronic system, this can be in the form of release of documents through network. There is also a need to keep track of every copy of the controlled documents so that updation of the same can be done whenever changes are affected. The revision status of every copy needs to be compiled and can be in the form of master list of documents updated periodically. Old versions of the documents need to be removed from the work place and any obsolete copies that are kept for contract or referral purposes need to be clearly marked.

Record is a specific type of document and has to be controlled as per separate clause (4.2.4).

The examples of documents of external origin include technical requirements/drawings given by the customer, regulations, standards, codes and specifications. All such external documents are to be identified by suitable means and also their distribution has to be controlled.

A procedure for control of documents has to be documented, which should describe the responsibility of each of the activity for control of documents. For example, who is responsible for approval of various types of documents (manual, procedures, instructions, etc)? What is the methodology of identification of each of the documents including revision status? How to ensure that latest documents are available at point of use? What is methodology of incorporating changes in documents?

How to Implement?

Document control is basically about making sure that the document which is in use is the right document that is it is the applicable document, the latest issue relating to the work being done. This is important for the people in the organization to have the correct/latest information if they are to do the job effectively. The term 'Document' is used to cover the information content in various media such as written documents, computer hard disk, CD-ROM, Audio tapes or posters. With the widespread use of computers, it has become relatively easy to comply with the requirements of document control. For example, a simple rule could be that any paper copy is uncontrolled.

It is always advisable to keep the number of copies of controlled documents to absolute minimum. IS/ISO 9001 requires that the information is to be kept up-to-date but does not specify how this is to be done. By taking advantage of the complexity, the simplest and most practical method should be adopted for document control.

Any changes of controlled documents should be reviewed and approved by an appropriate person, normally the original document approving authority. In case of electronic documents, the use of password control access combined with date of approval is also a way of indicating the approval status.

4.2.4 *Controls of Records*

> Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

What Does This Mean?

Records capture what happened and form the objective evidence that the activity has been carried out as per the established procedures. The record requirements have been identified in IS/ISO 9001 and they need to be properly retained. Records should not normally be altered. The need is one of identification, correct filing and ensuring ready availability for retrieval if needed. Archiving and when and how they are finally destroyed also needs to be covered. Lastly it is mandatory to document a procedure for control of records.

How to Implement?

Records need to be carefully kept and hence needs to be controlled. It would be worthwhile to establish a register of records, where they are stored or who operates them so that they can be easily retrieved. The important task is identification, copy filing and ensuring that they are readily available when needed.

The procedure for control of records should describe the methodology for the identification of various types of records, their storage, how these are protected to prevent damage, how these could be easily retrieved, what is the retention time of each type of record and how the records are disposed off.

Records include computer files. The above procedure should ensure that computer files are backed up on a regular basis, say, with at least one copy offsite. This can be supplemented with monthly copy of all the files for long-term storage so that one can always go back to the records of that month. Along with the computer records, the programme that is used to create them is also required to be stored for retrieval of the records when required.

The organization should identify how long each type of records needs to be kept and in some instances, retention periods may also be dictated by statutory or regulatory requirements, final requirements and possible product liability claims.

5 MANAGEMENT RESPONSIBILITY

Implementation of the quality management system is top management's responsibility and the requirements given in this clause are the responsibility of top management. In IS/ISO 9000, the top management is defined as 'the person or group of people who directs and controls an organization at the highest level. Top management has the responsibility to meet all the requirements given in **5.1** to **5.6** of IS/ISO 9001. Each of these requirements is explained in detail along with the role that top management is expected to play in fulfilling these requirements.

5.1 Management Commitment

> Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:
>
> a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
> b) establishing the quality policy,
> c) ensuring that quality objectives are established,
> d) conducting management reviews, and
> e) ensuring the availability of resources.

What Does This Mean?

Commitment is deep involvement by taking concrete and effective actions. IS/ISO 9001 indicates the areas where top management commitment is needed to implement a quality management system. Top management need to demonstrate and provide evidences that it has ensured for development, maintenance and continual improvement of the quality management system through proper communication, establishing a quality policy, establishing quality objectives, conducting management review meetings and providing the required resources.

How to Implement?

Based on the size of the organization, the Chief Executive or a group of senior management personnel will have to take on the responsibility to implement this clause. Top management, after ensuring development of a quality management system for the organization will have to ensure that it is maintained and continually improved through the following actions:

a) Communicate to all personnel in the organization the importance of meeting the customer's needs including statutory and regulatory requirements relating to the product and/or service, to achieve customer satisfaction. Evidence of this could be provided by maintaining a record of circulars issued, training conducted, product and/or service related meetings held, and other internal directives issued to ensure customer, statutory and regulatory-requirements are satisfied.

b) Establish a Quality policy, which is appropriate for the purpose of the organization. For other requirements of quality policy, *see* **5.3**.

c) Establish measurable quality objectives at the organization level and at department levels. For other requirements of quality objectives, *see* **5.4.1**.

d) Conduct management review meetings to review the progress, maintenance and improvement of the quality management system and take timely action if any weaknesses are found in the quality management system (*see also* **5.6**).

e) Provide necessary resources to maintain and improve the quality management system (*see also* **6**).

5.2 Customer Focus

> Top management shall ensure that customer requirements are determined and are met with the aim enhancing customer satisfaction (see 7.2.1 and 8.2.1).

What Does This Mean?

Meeting customer requirements is the primary aim of any organization. Top management must create focus throughout the organization for understanding the needs of its customers and finding ways to meet these needs. Since different customers may have varied needs it is very important for the top management to lay down methods to understand their needs and translate them into products and/or services that will satisfy the customer.

How to Implement?

Customer requirements can be determined through enquiries, tender documents, meetings/discussions with customers, customer/market surveys, customer feedback, complaints, studying competitors product and/or services, benchmarking, customer drawings, customer specifications, etc. Once these requirements have been determined they need to be met for ensuring customer satisfaction. Customer focus also includes factors like timely delivery, defect free delivery, cost reductions, design improvements, etc. Enhancing customer satisfaction can be achieved by understanding the customer perceptions or implied needs and providing for it accordingly, for example, additional features, functions, better after sales services, etc.

5.3 Quality Policy

> Top management shall ensure that the quality policy:
>
> a) is appropriate to the purpose of the organization,
>
> b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
>
> c) provides a framework for establishing and reviewing quality objectives,
>
> d) is communicated and understood within the organization, and
>
> e) is reviewed for continuing suitability.

What Does This Mean?

Quality policy is the overall intentions and directions of an organization related to quality as formally expressed by top management. The quality policy must be appropriate for the purpose of the organization, must express commitment toward improving a quality management system, be able to guide in the framing of objectives and should be communicated to all employees. The policy must be reviewed from time-to-time.

How to Implement?

The top management while framing the policy should ensure that the following are included in the policy:

a) Commitment to meet the requirements, for example, requirements of the customer, other stakeholders, statutory requirements, quality management system implementation requirements etc.
b) Commitment to continually improve the quality management system.
c) Framework or basis or broad areas establishing quality objectives (sometimes quality objectives could be included in the policy itself).

Once the policy is formulated it must be publicized and explained to all employees so that they understand the policy. This can be done through display of the policy at various locations in the organization including intranet, internal newsletters etc, and also covered in training programmes/other meetings. The policy should be reviewed from time-to-time, preferably in the management review meeting to ensure its suitability to the changing market situations and business environment of the organization.

5.4 Planning

5.4.1 *Quality Objectives*

> Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

What Does This Mean?

Quality objectives are goals to be aimed for. They are generally based on the quality policy and are normally specified for relevant functions and levels in the organization. Objectives must be fixed for all areas of the quality management system including those that are directly required for realization of the products and/or services. The objectives fixed should be such that they can be measured by fixing their targets and that they are achievable.

How to Implement?

Top management should identify all the areas for which objectives need to be fixed. Determine appropriate targets for each of these areas. These targets should not only be measurable but achievable. Examples of areas for fixing objectives include

a) Company level objectives that enables the organization to achieve its quality policy,
b) Department/function level objectives to enable achievement of organization level objectives,
c) Process level objectives to help achieve higher levels of efficiency in the processes, and
d) Product and/or service objectives that help to fulfil customer needs and expectations.

Quality objectives should not be open ended but should have a time frame fixed for achievement. Many organizations use the SMART method for determining the objectives. ***SMART*** means:

S — specific, ***M*** — measurable, ***A*** — achievable, ***R*** — result oriented, ***T*** — time frame.

While fixing quality objectives, it should be ensured that they are consistent with the quality policy, for example, if quality policy says that "We will ensure customer satisfaction", then the objectives should be fixed relating to marketing, product and/or service quality, delivery, servicing, etc, as these have a direct relation to customer satisfaction.

Some examples of quality objectives are given below:

a) To have x percent market share in product lines,
b) To launch at least one new product and/or service every year,

c) To achieve productivity level of y percent,
d) To have rejection levels not exceeding z percent,
e) To achieve a level of x percent on time delivery,
f) To answer all telephone calls within three rings,
g) To ensure no customer waits for more than 'x' minutes for service, and
h) To ensure training for y percent of employees for at least 'x' man-days in a year.

5.4.2 *Quality Management System Planning*

Top management shall ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

What Does This Mean?

Quality planning is defined as part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives.

Quality management system planning is required to be carried out in two stages. In the first stage we plan for implementing the system and in the second stage we plan for achieving the quality objectives set. Further as the system matures and the objectives change planning will have to be an on-going activity to ensure that these changes are implemented smoothly and the integrity of the system is not affected.

How to Implement?

In the initial stage of quality management system planning we need to determine the processes of the management system, their interaction, and the methods by which effective operation and control will be carried out. Further we will also need to define responsibilities and determine the resources to be provided for implementing the system and the information necessary to monitor the processes and systems.

In the next stage we will have to plan how the objectives will be achieved. This will involve planning of the detailed activities to be carried out to achieve each of the quality objectives including providing appropriate resources for the activities to achieve the end results and defining the responsibilities of the various persons.

As the quality management system is implemented and improved upon, changes to the system are bound to occur. Therefore, these changes need to be planned in a manner which will not compromise the integrity of the system. This can be done by having a defined and documented process for change. For example, if a new process is to be introduced, people working on these processes will need to be retrained, new work instructions will need to be prepared, new formats may need to be developed for recording information etc, and the entire process needs to be monitored for effective transition.

5.5 Responsibility, Authority and Communication

5.5.1 *Responsibility and Authority*

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

What Does This Mean?

Responsibility defines the area in which the persons are able to act and for which they are accountable. Authority is power or right given to a person to take actions or make decisions. Top management should frame the responsibilities and authorities for all functions/persons and communicate the same to the concerned persons and ensure that every person in the organization is aware of his responsibilities and the authority he has in respect to his function/job.

How to Implement?

Top management should clearly define the responsibilities of each function. These should then be communicated to the concerned personnel so that they are aware of what they are supposed to do in the discharge of their duties. Job-wise responsibilities help at the lower levels where more than one person may be doing the same job like, operators in an assembly or machining line. In the case of senior personnel where one person is looking after more than one function, then responsibilities should be defined person-wise. The amount of authority given should match the responsibility given to that person.

5.5.2 *Management Representative*

> Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:
>
> a) ensuring that processes needed for the quality management system are established, implemented and maintained,
>
> b) reporting to top management on the performance of the quality management system and any need for improvement, and
>
> c) ensuring the promotion of awareness of customer requirements throughout the organization.
>
> NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

What Does This Mean?

One member of the management should be appointed as management representative having responsibility for managing the quality management system. An outside person (for example, Consultant) cannot be made the management representative.

How to Implement?

Select a senior person within the organization and appoint this person as the management representative. The appointment can be made through a letter or can be defined in the manual against the corresponding clause. In small organizations the owner or proprietor or partner can himself be the management representative. Along with his other responsibilities, MR also has responsibility for the following activities:

a) Ensure that quality management system processes are established, are implemented in all the areas and maintained properly such that integrity of the system is not compromised,

b) Report periodically to the top management on how the system is performing and identify areas that need to be improved, and

c) Promote the awareness of customer requirements throughout the organization through training, internal meetings, formal and informal meetings with the customers, participating in the design review process, timely handling of customer complaints, etc.

5.5.3 *Internal Communication*

> Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

What Does This Mean?

Good and effective communication is essential for the quality management system to be implemented and feedback on the effectiveness of the quality management system should be appropriately communicated. A proper system of communication needs to be established at all levels so that required information reaches the right person at the right time. Information should be clear and appropriate to the person receiving it.

How to Implement?

Top management should ensure establishment of processes for determining the different types of information that needs to be communicated, the persons who will be receiving the communication and then decide the means or methods of communication that will be used within the organization. Any communication process should be able to:

a) Send and receive information quickly between sender and receiver,

b) Ensure no information is lost or distorted during the process of sending and receiving, and

c) Builds trust between sender and receiver.

The communication within the organization can include information relating to opportunity for improvement in business processes, customer satisfaction index/results of surveys, shortfall in performance processes, etc.

Some of the methods of communication that could be adopted include:

a) Formal and informal meetings,
b) Circulars,
c) Notice boards,
d) E-mail,
e) Newsletters, and
f) Monthly production plans/schedules.

5.6 Management Review

5.6.1 *General*

> Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
>
> Records from management reviews shall be maintained (see 4.2.4).

What Does This Mean?

Review is an activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives. Top management must review the organizations 'quality management system on a regular and planned basis to ensure it is functioning effectively and continues to be suitable and adequate for the organizations' functioning. Apart from reviewing the functioning of the system, the review should also assess opportunities for improvement, identify weak areas and determine if any changes are needed to strengthen the system. Further the management review should also include review of the quality policy, quality objectives, and its achievement. Records of management reviews should be maintained.

How to Implement?

An annual meeting plan should be prepared which should indicate the frequency of holding management review meetings. This will help the concerned persons including the top management to prepare and participate for the meeting and collect the information needed for discussion during the meeting. A meeting notice can be issued prior to the meeting date containing the agenda for the meeting. This will ensure participation of the concerned persons and also facilitate in giving a direction to the meeting. The minimum input points that must be discussed in the meeting is given in **5.6.2** of IS/ISO 9001.

Management review meetings should not be used for discussing day-to-day problems. It should be used for discussing broader issues, trend in the system, new business opportunities, resource requirements, weak areas needing attention etc. Management reviews should also be used for discussing long-term corrective action and identify opportunities for preventive action.

Records can be maintained in the form of Minutes of meeting, which will contain the subjects discussed, actions to be taken, time frame, responsibility for the action etc.

5.6.2 *Review Input*

> The input to management review shall include information on:
>
> a) results of audits,
> b) customer feedback,
> c) process performance and product conformity,
> d) status of preventive and corrective action,
> e) follow-up actions from previous management reviews,
> f) changes that could affect the quality management system, and
> g) recommendations for improvements.

In order to maintain consistency, management reviews should, as a minimum, review the following:

a) Quality policy, its continuing relevance and changes, if any, to be made to the policy;

b) Quality objectives and their achievement;
c) Corrective action to be decided for areas where objectives have not been met;
d) Internal and external audit results and action taken thereon;
e) Feedback received from customers including complaints;
f) Performance of the various processes of the quality management system;
g) Product and/or service conformity trends like incoming, in-process, final inspection, product and/or service nonconformance and customer rejection;
h) Corrective and preventive action in-hand and those completed;
j) Improvement projects identified;
k) Changes, such as, new regulatory requirements, new processes, new equipment and changes in business policies, which may affect the quality management system;
m) Actions taken on the decisions of management reviews;
n) Training needs already identified;
p) Supplier performance/problems; and
q) Identified gaps in the resources, for example, human, facilities and equipment.

5.6.3 *Review Output*

> The output from the management review shall include any decisions and actions related to:
>
> a) improvement of product related to customer requirements,
> b) improvement of the effectiveness of the quality management system and its processes, and
> c) resource needs.

The review output can be maintained in the form of minutes of meeting which will record all the information discussed in the meeting. The minutes can also indicate the persons who participated in the meeting. The responsibility of the persons including time frame for implementing the decisions of the management review should also be recorded. IS/ISO 9001 also requires that the following information must be included in the minutes as a part of the decisions from the management review:

a) Actions to be taken to improve effectiveness of quality management system,
b) Actions to be taken to improve process performance,
c) Actions to be taken to improve products and/or services specifically in relation to customers' needs and expectations, and
d) Resources needed to improve the quality management system, if any.

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

> The organization shall determine and provide the resources needed:
>
> a) to implement and maintain the quality management system and continually improve its effectiveness, and
> b) to enhance customer satisfaction by meeting customer requirements.

What Does This Mean?

One needs to plan and provide the various resources needed to implement, maintain and improve the effectiveness of the quality management system keeping in view the broader objectives of meeting and enhancing customer satisfaction.

The above resources would include material, plant and machinery, buildings, facilities, services, human, testing equipment and financial resources. Depending upon the needs and circumstances such as new contract and new market requirements, the above resources should be reviewed and provided.

6.2 Human Resources

6.2.1 *General*

Personnel performing work effecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

Competent personnel are vital resource for any organization. Identifying and providing the right human resource will ensure that the organization functions smoothly and is able to fulfil the needs of the customer.

Competence is defined as demonstrated ability to apply knowledge and skills. A person becomes competent through a combination of education, training, skills and experience. Persons assigned various tasks will need to have a right combination of these to be competent to discharge his duties satisfactorily. It is not necessary for the personnel to have all the four competence requirements but only those which are needed for accomplishing the designated job.

In any organization people who are assigned to carry out the various activities need to be competent to carry out that activity. This is all the more critical in a small organization where many people have multiple responsibilities.

6.2.2 *Competence, Awareness and Training*

The organization shall:

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that is personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

What Does This Mean?

The organization should determine the competence needed for each of the quality related activities carried out and compare it with the present competency levels of the person carrying out that activity. In case the competency levels of the persons are lower than that required, appropriate action should be taken to improve the competency levels. Further after taking the necessary action, evaluate whether this was adequate to meet the requirements of the job.

The organization should also make its personnel aware of the relevance and importance of their activities in achieving the objectives of the organization. Records of the competency levels needed including education, skills, training provided and experience of the personnel should be maintained.

How to Implement?

Identify all activities that are critical for achieving product and/or service quality and for the smooth functioning of the quality management system. For each of these activities, determine the level of knowledge, qualification, experience and skills needed to carry out the job successfully. This may be done as part of the job description. Having done this, determine the qualification, experience and skills of the persons executing the job. Match this with the requirements for the job to find out if the person is competent or not and identify gaps, if any. The possible areas to identify additional training would include outcome of the internal audit, corrective action and preventive action.

In case the requirements do not match then determine what kind of training or other actions will be needed to upgrade the competency level of the person to meet the requirements of the job. The organization should take suitable action to ensure that the competent person carries out the job.

Training in an organization should always be an on-going activity. Hence training should be planned taking into consideration the requirements of the job and the requirements of the organization. Training may be on the job, or through external means. Training can also be job specific or general in nature. General training could include training on quality management system requirements, good housekeeping, quality improvement, team building, managerial skills, etc. It needs to be ensured that the training provided will help the person to improve in discharging his/her duties in a better manner.

After providing training to a person, the effectiveness of the training has to be formally evaluated, which can be done in many ways. For example, a test may be conducted at the end of the training programme of the performance can be evaluated on the job output of the person after a reasonable period.

The organization, through various means like training, counselling, meetings etc, must make the personnel aware of the importance of their activities and how they contribute to the overall achievement of objectives.

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software), and
c) supporting services (such as transport or communication).

What Does This Mean?

Infrastructure is defined as a system of facilities, equipment and services needed for the operation of an organization. Infrastructure means the basic facilities, equipment, installations, the buildings, the working areas, utilities like power, steam, water, services like telecommunication, computers and its softwares, and the transportation system for the safe movement of products within and outside the organization. Organizations need to identify the type of infrastructure needed keeping in view the product and/or service being produced and delivered. As the organization grows and as new products and/or services are added, the existing infrastructure will need to be reviewed and provided to meet the new requirements.

It is also necessary to maintain the infrastructure in operational condition to ensure it gives the desired output and is able to deliver products and/or services that meet customer requirements. This usually means having preventive and corrective maintenance plans and also a replacement policy for old and outdated infrastructure.

6.4 Work Environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

What Does This Mean?

Work environment is the set of conditions under which work is performed. Work environment involves the physical conditions under which product and/or service has to be realized. Physical factors include, working conditions like temperature, humidity, noise, lighting, cleanliness, sanitation, hygiene, ergonomic, pollution hazards etc. It is very important to manage all these conditions to ensure that the products and/or service is produced in the stipulated environmental conditions. It should be noted that IS/ISO 9001 talks only of those work environment conditions necessary for producing conform/product and/or service, and not for the employees. However, providing proper work environment will ensure that people will discharge their duties effectively and efficiently.

Social conditions like people, work culture, organizational ethics, etc, may also be considered to be maintained for better working environment.

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product.
b) the need to establish processes, documents, and provide resources specific to the product.
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.

d) records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of the planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

What Does This Mean?

Before manufacturing a product or service delivery, it is necessary that all the processes in this regard are properly planned, which include planning for the requirements of the product and/or services, the processes, documents needed, resources needed, verification and validation activities to be carried out and criteria for acceptance.

How to Implement?

Prepare a process flow chart or list down all the activities involved in the manufacture and delivery of a product and/or service. For each of the activities/process determine the following:

a) Objectives for the product and/or service;
b) Characteristics of the process/activity;
c) Resources needed to complete the process/activity;
d) Parameters to be measured for the process/activity/product and/or service;
e) Responsibility for the process/activity;
f) Documents needed for the process/activity (process sheets, drawings, specification sheets, work instructions, etc);
g) Validation and verification required for the process/activities/product and/or service; and
h) Records needed to be maintained for each of the activities/process/product and/or service.

The above details can be documented in a quality plan or control plan or a checklist. This plan needs to be prepared for all the different products an organization makes or offers. These plans have to be revised whenever changes to the product and/or service or process are made. Authority for changes should be defined in order to maintain control.

The planning process should be as comprehensive as possible to ensure no or fewer problems at production and delivery stage of a product and/or service.

7.2 Customer-Related Processes

7.2.1 *Determination of Requirements Related to the Product*

The organization shall determine:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements related to the product, and
d) any additional requirements determined by the organization.

What Does This Mean?

Find out all the requirements/details related to the product and/or service before accepting an order. These will include

a) Requirements given by customer;
b) Requirements known to the organization based on end use of the product and/or service;
c) Requirements laid down by national/international standards, Government bodies, etc; and
d) Requirements known to the organization through past experience, feedback, test reports, etc.

How to Implement?

Determine customer requirements by studying his purchase order, specifications, drawings etc. Talk to the customer to collect further details which are not indicated in any of the above documents. If an order is received over the telephone, note down the details and then send a communication to the customer confirming the details noted down. This is to confirm that customer's requirements have been correctly understood. For organizations that are making standard products and/or services, customer surveys/feedback will go a long way in helping them determine requirements. Based on the end use of the product and/or service and its own experience, organization should determine requirements that will be needed but not stated by the customer. For example, material to be used for individual parts of a product; ingredients used in the dish served in a hotel. Go through the national/international standards, regulations etc, relating to the product and/or service to determine unstated requirements relating to the product and/or service. Use data collected from past designs, customer feedback, and competitors' products and/or services to determine additional requirements for the product and/or service. All these informations will comprise the requirements related to the product and/or service. Some of the examples of the above referred unstated requirements may include as follows:

a) For consumer goods, safety fuse has to be built-in to protect the user from shocks,
b) Hotels are expected to maintain a minimum level of hygiene in the work place to prevent the food from getting contaminated and harming the customer,
c) Textile mills are not allowed to use certain types of dyes in the printing and coloring process, and
d) Organizations are not allowed to use child labour.

7.2.2 *Review of Requirements Related to the Product*

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (for example, submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

What Does This Mean?

All requirements relating to the product and/or service have to be reviewed and any requirements that are not clear are resolved. Further, if some additional information is required relating to organization from the tenderer. The main emphasis is that there should be no conflict in the requirements of product then a potential customer wants to that have been understood by the organization. After completing understanding the product requirements, the review then to decide whether the organization has the ability to fulfil the customer requirements. Where verbal orders are received, organization should have a system to confirm to the customer the requirements. Further, when order requirements are changed, by the customer or by the organization even after agreeing to contract requirements organization should have a system to amend relevant documents and concerned persons be informed of the changes.

How to Implement?

A cross-functional team from various functions should preferably review the total requirements. This will ensure that different departments/functions are aware of the requirements and can plan for meeting the requirements. Organization should accept an order only after a review is completed and requirements understood. For standard products and/or services, the review can be as simple as comparing the customer requirements with standard specifications/catalogue for the product and bringing any differences to the attention of the customer for resolving the same. Verbal/telephone orders should be recorded and confirmed back to the caller either by reading back the requirements or by sending a confirmation in writing. Similarly for orders received on computer system, an e-mail confirming the requirements can be sent as confirmation. Documentary evidence should be maintained to show that review has been completed. This can be done by either reviewing authority signing on the requirement sheet or prepare a separate review checklist and signing this document. After the review process is completed, if any changes are made to the order, these changes will need to be reviewed, agreed upon and recorded. Original documents will need to be amended and these changes informed to concerned personnel in the organization. This will ensure that the final product and/or service meets customer requirements and possibilities of disputes are reduced.

7.2.3 *Customer Communication*

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

What Does This Mean?

The organization should have a system for communicating with their customers. This should be two-way communication, that is inform customer about the organizations products and/or services, procedures etc, and receive feedback from them on product and/or service quality, performance, new requirements etc.

How to Implement?

Have a formal system of communication with customers. Let the customer know the various channels of communication available. Most communication to customers takes place through the sales department. Information to customers can be given through advertisements, product and/or service brochures, catalogues, specification sheets etc. Communication can also be done through personal contacts, E-mail, telephone, exhibitions, participation in seminars etc. Information from customers can be received through feedback forms, complaint system, enquiries, tender process suggestions and verbal feedback. This communication system helps in clearly understanding the requirements of the customer.

7.3 Design and Development

The process of translating customer needs into concrete products and/or services is known as designing. The process of improving existing products and/or services is known as development. Design is a critical activity since the products and/or service ability to satisfy the customer depends on the right design. A proper design process will ensure that the organization's products and/or services will be competitive in the market. The entire design process is shown in following the flow chart.

PRODUCT PLANNING
↓
DETERMINE DESIGN REQUIREMENTS
↓
REVIEW DESIGN REQUIREMENTS
↓
DESIGN PLANNING
↓
PREPARE CONCEPT DESIGN
↓
REVIEW CONCEPT DESIGN
↓
PREPARE PRELIMINARY DESIGN
↓
REVIEW PRELIMINARY DESIGN
↓
CARRY OUT DETAIL DESIGN
↓
REVIEW DESIGN CRITICALLY

↓
CONDUCT DESIGN VERIFICATION
↓
REVIEW AFTER VERIFICATION
↓
PREPARE PROTOTYPE
↓
CONDUCT DESIGN VALIDATION
↓
FINAL DESIGN REVIEW
↓
DESIGN RELEASE

(DESIGN CHANGE, if any to be incorporated into detail design after each review)

7.3.1 *Design and Development Planning*

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine:

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

What Does This Mean?

The total design activity should be planned taking into consideration all factors that contribute to the design process. Some of the factors that need to be considered are safety, health, environment, user friendliness, product disposal and any identified risks.

How to Implement?

A detailed design plan needs to be prepared. This plan should list down all the activities involved in the design process. Against each of these activities determine the following:

a) Inputs needed for the activity,
b) Resources needed to fulfil the activity,
c) Interfaces needed with other activities,
d) Persons responsible for carrying out the activity,
e) Different stages of review of the activities,
f) Output documents to be generated for each of these activities,
g) Time frame in which all these activities have to be completed, and
h) The design plan can be in the form of a control plan or a checklist. As a minimum the activities covered in 7.3.2 to 7.3.7 should be addressed in the design plan.

7.3.2 *Design and Development Inputs*

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include:

a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

What Does This Mean?

All information required for the design process and designing the product and/or service need to be obtained so that the design of the end product and/or service meets customer requirements.

How to Implement?

Identify all the sources from where information has to be obtained/collected. Examples of information to be collected for design and development inputs are:

a) Customer requirements needs and expectations,
b) Functional requirements,
c) Product and/or service performance requirements,
d) Information from industry standards and national/international standards,
e) Statutory and regulatory requirements for the product and/or service,
f) Environmental requirements,
g) Information from similar designs or previous designs,
h) Safety requirements,
j) Cost considerations, and
k) Any other information that will help in the design process.

When information for the design input is being collected, it has to be ensured that the information is clear, unambiguous and complete. Records of all the information need to be maintained.

7.3.3 *Design and Development Outputs*

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development output shall:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and service provisions,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

What Does This Mean?

The output of the design and development process should meet the requirements of the input stage. The output should be in a form that can be used for generating the product and/or service and any subsequent verification activity. All calculations, drawings and specifications generated during the design process should be recorded and maintained.

How to Implement?

Identify the persons/team which will carry out the design work. Ensure the team has been given all the requirements and information collected at the design input stage. Use failure analysis techniques to ensure design is capable of preventing problems. Keep a record of all data generated during the design process. Generate drawings and specifications of the product and/or service and its individual parts that will aid the manufacturing process. These drawings and specifications should also include performance requirements, verification requirements and acceptance criteria for the product and/or service. Generate bill of material indicating requirement for raw material, bought out parts and manufactured parts. Approve the output document before it is released to purchasing, manufacturing, inspection and to customers.

7.3.4 *Design and Development Review*

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

What Does This Mean?

Review of the design activities need to be carried out to determine and ensure that the design process is proceeding properly and that all customer needs are being addressed/met. Problems if any should be identified at this stage and suitable actions should be taken to address and resolve them.

How to Implement?

Carry out a review of the design activities at appropriate intervals to ensure the output at each stage meets input requirements. One person or a team of persons depending on the complexity of the design may carry out review. Except in the case of a very simple design, review should be done by a cross-functional team for better results. Stages of design review can be identified during the planning stage but as a minimum should be done after design output stage, design verification stage and before release of final design. Records of the review process should be maintained.

7.3.5 *Design and Development Verification*

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

What Does This Mean?

When the design work is completed, the output, that is, specifications, calculations and drawings need to be verified to ensure that they meet the input and customer requirements.

How to Implement?

Design verification is done as per methods identified in the design plan. Various methods can be used for the verification process. Some of these include

a) Perform alternate calculations to check if original calculations are correct;
b) Compare the new design with a similar or proven design;
c) Check all design documents independently for accuracy;
d) Test by preparing a prototype based on the new design; and
e) Use computer software, if available, to verify new design.

Verification will ensure that any mistakes and weakness in the design will be revealed and corrections can be made before finalizing the design. Records of all verification activities need to be maintained as they are important data for future designs also.

7.3.6 *Design and Development Validation*

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever applicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions shall be maintained (see 4.2.4).

What Does This Mean?

It has to be ensured that the design is capable of performing as per customer requirements in actual conditions of use. Prototypes of the product are subjected to tests in actual working conditions and results monitored to determine if product will meet specified requirements of use. It must be remembered that validation is not possible in many cases like structures, bridges, buildings, etc.

How to Implement?

Once the designs are ready prototypes are prepared and tested in actual working conditions. The results are evaluated and checked to verify if the product meets customer end use conditions. The prototypes are subjected to tests under different operating conditions and their results evaluated. Based on the evaluation, changes if any required, are made to the design before releasing it for production. It is suggested that customer also should be involved in the validation process. Feedback from validation also helps in future designs. In cases where validation is a very lengthy process, simulated or accelerated testing could be employed. In case of products, like buildings, structures, etc, validation may be done on scale models and results extrapolated to the actual product. In case of software, the design is validated by the customer and feedback is obtained on an ongoing basis. Records of all validation activities need to be maintained.

7.3.7 *Control of Design and Development Changes*

> Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.
>
> Records of the results of the changes and any necessary actions shall be maintained (see 4.2.4).

What Does This Mean?

It is necessary to identify all changes that the design is subjected to during the design process and after delivery of the product and/or service. These changes should be properly recorded in the original design document. All changes must be reviewed, verified and validated as appropriate. Effect of the changes on products and/or services already supplied should be evaluated.

How to Implement?

When a change is made to the design, record the changes on the original document. Indicate the nature of change, reasons for change, date on which change was carried out, person who has authorized the change etc. Review the changes to ensure that other aspects of the design are not affected. Verify/validate the changes to ensure the product and/or service meets customer requirements.

Inform every one involved in the design process and product and/or service realization process of the changes carried out. Inform the customer of the changes and its impact on the end product and/or service.

7.4 Purchasing

7.4.1 *Purchasing Process*

> The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
>
> The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

What Does This Mean?

Purchased material, consumables, components, assemblies and services form an important part of an organization's product and/or service realization processes that directly affect the quality of its end product and/or service. The purchasing activity should be properly planned, controlled and executed in a systematic manner. There is need to evaluate and choose suitable suppliers which can meet organization's requirements based upon a defined criteria. Further, the supplier should be made aware of the organization's quality requirements in detail to build a clear understanding of each other's needs. Close working relationship should be established with each supplier and regular feedback should be given to the supplier on the quality of their supplies.

All the above have also to be applied on the purchase of services like calibration, transportation, software, etc.

How to Implement?

The type and extent of control applied to the supplier and the purchased product and/or service should depend upon how critical the product and/or service being supplied is to the quality of product and/or service required by the organization, for example, the purchase of branded products and/or services would require minimal control and the obvious source of such products and/or services is a wholesaler or retail outlet.

Evaluation and Selection of Supplier

Suppliers should be selected on the basis of their ability to meet the following requirements:

a) Reliability of the supplier based on past experience or feedback from other users.
b) Are they capable of supplying as per organization's needs and requirements?
c) Are adequate resources like machinery, skilled manpower etc, available?
d) Is there a quality control or quality management system in place?
e) Are they approved by other well-known organizations or third party?

There are a number of ways of assessing the suitability of a supplier:

a) If a supplier's quality system has been approved by an accredited third party certification bodies (IS/ISO 9001 certification bodies like BIS) or bodies like Defence organization, Leading PSUs, Export Agencies, etc, then this can be used as a starting point for its evaluating a supplier for its ability to meet organization's requirement.
b) Previously demonstrated capability and performance in supplying the same or similar kind of product and/or service to the organization or to other organizations. For this, it is essential that a detailed record of past supplies and their quality status should be available by which it will be possible to evaluate the quality capability of a supplier. These records may contain details of (i) Quantity supplied, (ii) Quantity rejected, (iii) Adherence to delivery schedules, and (iv) post delivery problem resolution.
c) Suppliers' capability may be evaluated by means of a visit to their premises to assess the technical capabilities, quality system in operation, commercial operation, capabilities of personnel working in the premises etc.
d) Under certain circumstances, products being manufactured by supplier may be subjected to detailed verification, inspection or type testing as a means of supplier evaluation.
e) Purchasing products from the suppliers bearing Standard Mark like ISI, CE and Agmark.

It may also be considered that purchase in smaller quantity or for a trial period may be made to assess the capability of the supplier to meet our needs. This arrangement should be reviewed at the end of the trial period for establishing regular supplier relationship.

Whatever may be the basis on which selection of the supplier is done, the same should be documented.

If a supplier cannot be found who meets all the required criteria and some minor deficiencies are observed, then these should be brought to the notice of the supplier and all efforts should be made to have the deficiencies removed. This is all the more true in the case of system deficiencies like lack of procedures, non-availability of records, etc.

There is a need to regularly monitor the performance of the supplier to supply products and/or services as per requirements of the organization. This should be followed by a periodic re-evaluation for continuation of supplier relationship. Suitable provision should be provided in the system for addition and deletion of vendors based on their performance.

7.4.2 *Purchasing Information*

Purchasing information shall describe the product to be purchased, including where appropriate:

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

What Does This Mean?

In order to ensure that the supplier has correctly understood the purchase requirements, the communication with the supplier should be clear and unambiguous. Requirements should preferably be given as a written purchase order, it is advisable that they are backed up by a written confirmation to avoid any misunderstanding or communication gap, whenever verbal instructions are given.

Irrespective of whether the order is written or verbal, it may be useful to keep an internal record of what was ordered so as to confirm that whatever was asked for has been received.

This part of the purchasing requirement also deals with the optional details that should be included in the purchase order. The extent to which the details listed in items (a) to (c) apply depends on the extent to which the goods and services being ordered affect the quality of the products and/or services.

How to Implement?

The organization's purchasing data should define the complete technical requirements to ensure the quality of the procured product and/or service. This information must be properly communicated to the supplier. In addition to the commercial terms and conditions, the following technical information should also be included in the purchase order:

a) Technical decision of the product and/or service, which could be in the form of a product and/or service catalogue number, specifications, drawings, etc;
b) Packaging specifications;
c) Quantity ordered;
d) Delivery schedule;
e) Place of delivery;
f) Method and location for verification/inspection; and
g) Supplier quality certification.

Following additional requirements may also be included in the purchase order, if considered necessary:

a) Suppliers certification of the product and/or service quality;
b) Procedures and processes to be used by suppliers, for example, production quality plans;
c) Equipment approved for use by the supplier;
d) Qualifications of the suppliers personnel, for example, certificate of welders, licence of architects, etc;
e) Quality control or quality system requirements of the supplier;
f) Place of product and/or service verification;
g) Verification by (your) customer at (your) suppliers' premises;
h) Product and/or service preservation, handling and transportation requirements;
j) Requirement of intermediate product and/or service approvals (for example, testing of welds on pressure vessels before clearing for further operation);
k) Approval of deviations/concessions in the product and/or service quality; and
m) Third party inspection requirements.

The organization should review the purchase order before release for correctness and accuracy and the authority of the person carrying out this task should be clearly established. Any amendment to the purchase order at a later date should also be preferably reviewed and authorized by the functionary who had released the original purchase order. A system to ensure the prompt and clear communication of such modifications/changes to suppliers should be established and implemented.

7.4.3 *Verification of Purchased Product*

> The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
>
> Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

What Does This Mean?

The system of verification of the product and/or service being supplied by the supplier should be clearly stated by the organization in the purchase order. The verification system should be agreed to between the organization and the supplier before finalizing the purchase order.

How to Implement?

Some example for the methods used for verification/inspection of the purchased products include:

a) The organization relies on the supplier quality assurance system,
b) The supplier submits inspection test data and statistical process control records,
c) 100 percent or sampling inspection/testing by the organization at receipt stage,
d) Inspection at suppliers' end before dispatch, and
e) Engaging any third-party inspection agencies.

The organization must clearly indicate in the purchase order to the supplier if the ultimate customer will be carrying out any verification activity at supplier's premises.

The supplier should provide all facilities and records to aid verification/inspection. The level of verification activity should be commensurate with the kind of product and/or service being verified. The final responsibility of delivering a quality product and/or service to the purchaser lies with the supplier and not the purchaser.

Guidance given for control of nonconforming products under **8.3** would also apply to the purchased products.

7.5 Production and Service Provision

7.5.1 *Control of Production and Service Provision*

> The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:
>
> a) the availability of information that describes the characteristics of the product,
> b) the availability of work instructions, as necessary,
> c) the use of suitable equipment,
> d) the availability and use of monitoring and measuring devices,
> e) the implementation of monitoring and measurement, and
> f) the implementation of release, delivery and post-delivery activities.

What Does This Mean?

The process of implementing the design or converting a design into a product and/or service is known as result producing process or production. Production is also the process used to repeatedly produce product and/or service to the same standard each and every time. The production process needs controls to maintain required standards. This can be done by controlling the product and/or service through verification or controlling the process through which the product and/or service passes. Generally it is a combination of both these that are used to ensure consistent quality.

This clause defines the controls required to produce and supply or deliver a service. Various factors that are involved in the control of processes are given below:

a) Information giving full details of the product like dimensions, finish and shape, which are needed to ensure customer requirements are achieved.
b) In order to carry out the work, the worker will need to be provided with suitable instructions, which are clear and precise to ensure desired quality of product and/or service is achieved.
c) The equipment selected to produce the product and/or service should be capable of achieving the desired accuracy over a considerable period of time. This will also mean that the equipment be suitably maintained during use.
d) Measurement of the process is a key factor in controlling it. This will mean providing the devices required to measuring the product and/or service parameters and also monitoring process parameters.

e) Monitoring and measurement of products and/or services and processes should be done as defined in the specification sheets. These monitoring and measurement must be done at defined frequencies to ensure the process is under control and the resulting product and/or service meets requirements.

f) Verifying that product and/or service meets requirement and can be sent to the customer is known as realizing the product and/or service for delivery. This is usually known as pre-delivery inspection or final inspection. Once released the product and/or service is packed as per specification and delivered to the customer. Many products need to be installed after delivery if agreed in the contract. They may also require servicing over a specified period of time. These activities are known as post-delivery activities.

How to Implement?

When the design has to be converted into a product and/or service, the organization will need to determine the production/provision processes that will be used in the production of the product or provision of service. These processes will then have to be qualified to ensure that they are capable of achieving the accuracies or tolerances required. If existing processes are to be used, then the capability of these processes need to be matched with the tolerances required for the product and/or service. Determine the routing of the product and/or service through these processes. This routing plan is known as the process flow chart or route sheet. This document will contain all the details of the operations to be carried out including the specifications for the operation, dimensions etc, to be achieved. These plans create the basis for work to be carried out under controlled conditions, which are described below:

a) The information that describes the characteristics of the product and/or service can be in the form of drawings, process sheets, specification sheets, control plans, samples, etc.

b) The worker will have to be provided with proper instructions to carry out the job. If the employee is experienced, then a simple instruction should suffice, if not, a detailed instruction may be necessary to ensure the job is carried out properly.

c) The equipment selected should be capable of achieving the desired product and/or service parameters in terms of accuracy. If existing equipment is to be used then the process capability of the equipment would be known and would help in determining if it is capable of achieving the tolerances required by the product and/or service. If new equipment is to be used then it is necessary to determine the process capability before starting the production process. Further the equipment needs to be maintained properly to ensure they deliver desired results. This is done through routine maintenance (daily cleaning, oiling, adjustments etc) and preventive maintenance (change of belts, internal cleaning, internal adjustments, replacement of worn out parts, cleaning filters etc).

d) Measurements need to be carried out as the product and/or service goes through various production processes. These measurements need to be carried out on the product and/or service and process. Product and/or service measurement will mainly relate to Dimensions, Fit, and Finish etc. Process measurement will relate to Temperature, Pressure, Speed, Feed, and Time etc. Various devices will need to be provided for these measurements. It will need to be ensured that all monitoring and measuring devices needed are identified and provided before production starts. This will ensure that operator can determine when the required conditions/characteristics have been achieved.

e) Suitable conditions need to be created to ensure that monitoring and measurement activities are implemented. The details of monitoring and measurement to be carried out should be provided to the operator. The devices needed for monitoring and measurement should also be provided to the operator. The operator should be trained to operate these devices. Instructions should be available indicating when the monitoring and measurement should be done. If these need to be recorded then suitable formats should be provided. It is only when these conditions are fulfilled that monitoring and measurement can be implemented.

   Monitoring and measurement are crucial to determining the product and/or service characteristics and ensuring they meet requirements. If proper monitoring and measurements are not carried out at the appropriate time, one may end up with a large number of nonconforming products and/or services.

f) Controls are needed to ensure products and/or services in various stages of processing are released to next stage only after all activities related to that stage are completed. Stages of release include raw material and components kept in store, in-process stages and final stage when completed product and/or service is released for delivery to customer. It must be ensured that only conforming material, which has undergone all checks as per process documents are released.

Delivery of a product and/or service includes activities like proper packaging, handling and shipment to customer. It must be ensured that these activities are carried out in such a manner that product and/or service reach the customer in conforming condition.

Post-delivery activities are those that are performed after the product and/or service reaches the customer. These include Installation, Servicing, Technical support, Warranty, Maintenance support etc. Depending on the kind of product and/or service some or all of these activities will have to be planned for and provided to ensure customer satisfaction. Personnel will have to be trained to provide these services. These personnel will also have to be provided the requisite tools to carry out these services.

7.5.2 *Validation of Process for Production and Service Provision*

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable:

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4), and
e) revalidation.

What Does This Mean?

Processes whose results cannot be fully verified by subsequent inspection and testing of the product and/or service are known as special processes. In such cases, processing deficiencies become apparent only after the product and/or service has been put into use. These special processes are dependent on the process controls to achieve desired quality parameters on the end product and/or service. Some of the examples of special processes are Welding, Forging and forming, Soldering, Adhesive bonding, Heat treatment, Painting, Protective coating, Concrete pouring, etc.

Some examples of special process are given below:

Pouring of concrete — The strength of concrete depends on the quantity of cement, aggregates, and water to be mixed. The pouring of the mix has to be carried out by trained personnel to ensure proper flow of mix to all areas. This mix cures over a period of time and testing is done only after 28 days. If the test results are not acceptable then the entire concrete has to be destroyed and re-done afresh.

In a travel agency, incorrect information or wrong interpretation of data will only be discovered when attempting to travel.

At home when cooking food, the right quantity of ingredients are important if the correct taste and quality are to be achieved.

Special processes need to be validated or approved for the various process parameters and the optimum process parameters selected so that end results are consistent. The process parameters should be strictly followed to ensure the quality of end product and/or service. Processes have to be validated for the following:

a) The criteria to be used for approval of the process, namely, the tests to be carried out during approval stages that will confirm that the final product and/or service meets requirements.
b) The qualification of personnel who will operate the process, for example, welders certificate for pressure vessel welding.
c) Equipment which will be used for the process. The equipment should be capable of meeting/achieving the process conditions/parameters repeatedly.
d) Work instructions detailing the methods to be used for carrying out the process and the parameters to be used for the same.
e) Determine what records are to be maintained and what data are to be recorded which will give confidence that the process parameters have been followed and end results achieved.

f) The frequency with which the process will have to be revalidated and the conditions under which revalidation is required have to be decided. For example, change of operator, maintenance of equipment, when some parts of the equipment are to be replaced and change in operating conditions could all lead to revalidation of the process.

How to Implement?

Study the processes used in the organization and determine in which of them the results of the process cannot be measured easily or without damaging the product and/or service. These processes will be the special process.

Determine the equipment to be used in these processes, the personnel who will operate these processes, the process parameters to be monitored and the work instructions needed to operate these processes. Prepare a process control document containing the following:

a) Details of equipment to be used including make, type, capacity and accuracy.
b) Qualification of personnel who will operate the process, for example, Welders certificate, Training undergone on the process, Experience etc, to ensure personnel are suitable for the process being carried out.
c) Write down in detail the procedure to be followed in executing the process including details, like Temperature, Pressure, Time, Current, Voltage, Environmental conditions etc. For example, during heat treatment, temperature of furnace and time for which a specific part is heated, is critical for achieving the desired hardness. During welding, current and voltage are critical parameters. During painting, pressure, viscosity and humidity are critical parameters.
d) Once the above details have been decided carry out the process on sample pieces varying one parameter at a time and keeping the other parameters constant. Record the details of the process for each set of samples and verify the results. Freeze the set of parameters which give the optimum and desired result. Use these parameters to carry out the process in regular production.
e) Revalidate the process if any of the parameters are changed.

7.5.3 *Identification and Traceability*

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

What Does This Mean?

Products and/or services need to be identified during the realization process. Identification can relate to the product and/or service and/or to the inspection status (O.K., reject, under review, under test etc). Further if a product needs to be recalled back at a future date then it needs to be identified with respect to the batch or lot of production (batch number, date of manufacturing, month of manufacturing etc).

Product and/or service identification is needed when similar products and/or services are being realized and mix up needs to be avoided. This identification may not be necessary in many situations (for example, chemical industry where the process is continuous, the sequence of operations ensures that mix up does not occur.).

Identification with respect to inspection status is needed to determine whether a product and/or service has been inspected or not, and if inspected, whether it has been accepted or rejected. All these three status of inspection and test have to be suitably identified.

Traceability is needed when a product and/or service needs to be recalled due to any reason (for example, failure of parts in an automobile, defective medicines having adverse reactions on a patient etc). Traceability today is a critical requirement especially to meet statutory and regulatory requirements.

How to Implement?

Identify the stages in the process where the product and/or service needs to be identified, the method that will be used for identification and the records that will need to be maintained with reference to identification and traceability.

Product and/or service identification can be done in many ways, like:

a) Route cards that accompany the product and/or service through out the process;
b) Tags/Labels indicating the model, part number, operation number etc;
c) Marking on the product by marker, paint etc (for example, document in a courier company);
d) Punching marks on the product (for example, fabricated parts); and
e) Marking on a part of the product (for example, castings and forgings where the mark is cast or forged on the part itself).

Inspection status can be identified through:

a) Tags — O.K., Reject, Under Inspection, Review etc;
b) Coloured Bins — Different coloured bins for each of the three inspection and test status;
c) Paint mark, marker pen etc; and
d) Signature of authorized person.

For example, in a hotel the status of a room after a guest has checked out is indicated by Not ready sign. Once room service has cleaned the room and changed the linen, status is changed to Ready and the same is conveyed to reception.

Traceability needs to be maintained in product and/or service recall situations. For traceability purposes the records should clearly indicate the date of processing, the batch of the material used for producing the product, inspection details etc. The records should also indicate the customer to whom the product and/or service has been delivered so that if a product and/or service from a particular batch has to be recalled the identification of the customer is known.

7.5.4 *Customer Property*

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

What Does This Mean?

Any item that belongs to the customer and has been provided to the organization for producing the product and/or service is customer property. Examples of customer property include:

a) Raw material, Parts, Sub-assemblies, etc, given by customer for incorporating into the final product and/or service;
b) Drawings, Technical specifications, Standards etc, provided by the customer for producing the product and/or service;
c) Software provided by the customer for producing the product and/or service; (In outsourcing of data processing jobs customers provide the software for data entry and report generation);
d) Clothes given to Tailor or Dry cleaners for processing;
e) Film roll given to processor to develop and print the film;
f) Motor vehicle given to Repair/Service centre;
g) Valuables given by the customer to be kept by the organization for providing loan; and
h) Laptop, LCD projector, Black board etc, provided by the customer to the outside organization invited for conducting training programmes for the customer.

How to Implement

When customer property is received by the organization, it should be recorded in a suitable format. Details to be recorded can vary from product to product. After recording the details any discrepancy should be informed to the customer and records maintained of any communication made.

During the time the property is with the organization it should be taken care of properly and any damage or loss should be promptly informed to the customer. Some examples of implementation are given below:

a) Prepare a list of drawings, specifications, standards received and during use if any of these get damaged inform customer and ask for replacement;
b) Software received from customer should be tried out and any problems noticed in using the software should be reported to customer;
c) Clothes received by dry cleaners should be thoroughly checked and any stain marks, damages, etc, should be noted on the receipt and informed to the customer/person delivering the item;
d) In the case of film rolls received for processing, any defects noticed during the process of Developing should be informed to customer and further Printing should not be done till instructions are received from him;
e) When motor vehicles are received for Servicing or Repairs, the Engine number, Vehicle serial number, Registration number etc, should be recorded. Any damage/missing parts should be recorded and pointed out to the customer at the time of accepting delivery of vehicle for service; and
f) Valuables, like jewellary, registration papers given by the customer should be identified and recorded in a register and the details kept in a locker to prevent the same from falling into the wrong hands.

7.5.5 *Preservation of Product*

> The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent part of a product.

What Does This Mean?

Every product and/or service involves some kind of Identification, Handling, Packaging, Storage, Preservation, and Delivery etc. The nature and extent will depend on the kind of product and/or service involved. The main requirement is that the product and/or service maintains its conforming status once it has been certified as being a conforming product and/or service till the product and/or service is delivered to customer. The product and/or service can be at any stage of processing, for example, at raw material stage, in-processed materials or the finished product.

Identification — Conforming products and/or services should be suitably identified throughout the process till they are delivered to the customer. These could be done using Tags, Labels, Stickers, Coloured bins, Markings on the product etc, or separate stores/area being kept for such items.

Handling — Products and/or services should be handled in such a manner that conforming status is not changed. Delicate material like glass should be handled carefully, chemicals and pharmaceuticals should be handled using protective clothing to avoid contamination, Sterile material should be handled using gloves, Electronic equipment should be handled using special gloves to avoid build up of electrostatic charge, Liquids should be handled in containers that are suitable for the purpose to avoid spillage and containers should be cleaned properly when a new liquid has to be filled to avoid contamination.

Packaging — Should be appropriate for the product. Glass products should be packed in shock/impact absorbing material like foam or thermo Cole. Chemicals should be packed in non-corrosive material like glass, stainless steel, plastic containers etc. Bulk material like food grain, sand, coal, etc, could be packed in large containers. Large fabricated items may not need any special packaging except being properly tied down to the transporter.

Storage — All products should be stored in such a way so as to avoid deterioration during storage. The storage conditions/instructions should be indicated on the packaging or should be sent along with the product. Food products need to be stored at different temperatures, for example, Ice cream at –20°C, chocolates at 0 to 10°C. Electronic items need to be stored in dust free conditions, medicines in cool dry conditions, magnetic tapes and hard discs in non-magnetic environment.

Protection — Products should be protected from various environmental conditions till they reach the customer. Protection involves covering the product suitably to prevent deterioration, for example, Consumer products covered by polythene wrapping, Food products protected by nitrogen atmosphere within the packet, Bottled food products sealed with a foil cover at the lid, Products covered with shrink wrap film etc. Proper protection also ensures tampering does not take place.

7.6 Control of Monitoring and Measuring Devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall:

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) be adjusted or re-adjusted as necessary;
c) be identified to enable the calibration status to be determined;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See IS/ISO 10012 for guidance.

What Does This Mean?

This clause is applicable to those organizations that use monitoring devices and measuring equipment to verify that products and/or services meet customer requirements.

Monitoring normally means supervision and observation activities using appropriate monitoring devices. Monitoring devices normally deliver non-quantitative results and are not usually calibrated but validated.

Measurement normally means determining magnitude, dimensions, quantity or other such parameters using appropriate measuring equipment. Measuring devices normally deliver quantitative results (for example, weighing scale, thermometer etc) and are usually calibrated for accuracy.

Organizations will need to determine the parameters that need to be monitored and measured at the product and/or service realization stage. Further the methods for monitoring and devices to be used for measuring have to be determined at this stage. Organizations will also have to determine the process by which these monitoring and measurement will be done and provide necessary resources to carry out these activities and also record the same.

Based on the measuring equipment to be used for verifying compliance to customer requirements, organizations will need to determine how these will be calibrated, identified, stored, handled and their accuracy maintained during the period of their use. If measuring equipments are to be used for indication only then it may not be necessary to calibrate all these equipments. Therefore, it is necessary to decide which of the equipment need calibration, which may include:

a) Calibration means comparing the measuring equipment against a standard equipment which is of a higher accuracy to determine how accurate the equipment is and deciding whether it is capable of making measurements with the accuracy required for job/parameter to be measured. Calibration has to be done on a periodical basis based on the extent of use and also after any repair/maintenance of the equipment. The standard equipment used for calibration should have their calibration traceable to national or international standards and should be appropriate for the equipment being calibrated. These may have to be procured separately if not supplied with the measuring equipment (for example, standard test block supplied with micrometer, thickness standard supplied along with thickness gauge). Calibration can also be done through external agencies, who are authorized to provide such services.

b) The level of accuracy of calibration will depend on the type and accuracy of measurements being made with the measuring equipment. Normally the accuracy of measuring equipment will depend on the tolerance level of the dimension being measured and the skill level of the person who will carry out the measurement (for example, auto parts may require tolerance of 0.001 mm whereas a textile or dress manufacturer may need a tolerance of 1 mm or more).
c) Some equipment might need to be adjusted before use and re-adjusted during long periods of usage. This is mostly true of electrical measuring equipment where the pointer is adjusted from time-to-time. Other examples include counters, which need to be set to zero before start of counting.
d) All equipment that have been calibrated need to be identified suitably to indicate their calibration status (for example, through stickers, paint marks, small metal tags, etc).
e) Once calibrated, equipment that do not need adjustments, need to be sealed to prevent tampering/adjustments and to maintain their calibration status. If this is not done then the validity of measurement results could be suspected.
f) The measuring equipment should be stored in a way so as to avoid damage or deterioration of the equipment. The equipment should be handled appropriately so that the calibration status does not get invalidated. Further the equipment should also be regularly maintained to ensure its proper working order.

During use if it is found that the equipment is not working properly or its calibration status has been compromised, then the organization will need to assess the validity of previous measurements made with this equipment. This is to make sure that if a product and/or service has left the organization with incorrect specification then appropriate action is taken to correct this situation.

These days some measuring equipments are computerized and use various software for measuring the parameters. These software need to be validated through suitable means to ensure that they are performing the tasks correctly. Most software has self-validating programmes and they need to be periodically run to ensure accuracy of the test software and the equipment.

Records of all calibration activity need to be maintained. If calibration is done in-house then the details of measurement recorded during calibration will have to be maintained. If calibration is done from an external source then appropriate certificates should be obtained for the equipment calibrated.

How to Implement?

Organizations should determine the monitoring and measurement activity to be undertaken at the planning stage for product and/or service realization. These should be recorded on the control plan/quality plan.

In the case of monitoring the following need to be determined:

a) What is to be monitored (for example, parameters in a customer satisfaction survey, finish of cloth in textile mill, defects in weaving etc)?
b) How it will be monitored (for example, survey questionnaire, visual checking, go/no-go gauging etc)?
c) Who will do the monitoring? (Persons involved in monitoring need to be trained for the job as any mistake on their part can result in a nonconforming product and/or service.)
d) How this process will be validated (for example, regular eye check up of person doing visual inspection, counter check by actual measurement in case of gauging)?

In the case of measurement, the following need to be determined:

a) Kind of measurement to be carried out,
b) Accuracy required,
c) Conditions under which the measurement is to be carried out,
d) Who will carry out the measurements, and
e) Any other requirement given in the drawing or specification.

Based on the above, the measuring equipment to be used will need to be determined. The measuring equipment to be used may also be indicated on the control plan/quality plan.

Having done this, the organization will need to procure these measuring equipments or arrange for the monitoring devices so that monitoring and measuring activity can be carried out as planned. Where necessary, personnel will have to be trained for use of this equipment or devices. Appropriate procedures and formats should be provided to the persons carrying out this activity so that consistency is achieved and monitoring and measurement records are maintained.

Equipment used for measurement activity will not be accurate throughout its life or period of use and, therefore, needs to be calibrated from time-to-time. Calibration can be done in-house or can be arranged from an external agency authorized to carry out calibration work. For in-house calibration, the following factors need to be kept in mind:

a) Availability of appropriate procedures/instructions for calibration of various types of equipment.
b) The environmental conditions in which the calibration process will be carried out.
c) Availability of reference standards for calibration of the equipment.
d) The type of data to be recorded during the calibration process.
e) Frequency of calibration. This will depend on the usage of the equipment and the accuracy level required for the instrument.
f) Skill level of personnel carrying out the calibration work.

Equipment once calibrated need to be identified suitably to indicate the calibration status. This can be in the form of stickers, paint markings, tags etc. Persons using the equipment should be aware of the system used for indicating the calibration status so that they do not use equipment, which is not calibrated. Ideally the identification system should include date of calibration, the accuracy level of the equipment and the date of next calibration. It should also indicate if there are any specific restrictions on the use of the equipment.

Once the equipment has been calibrated, steps should be taken to prevent any tampering which would invalidate the calibration status. The level of protection will vary from equipment to equipment but should be appropriate for the equipment. Some methods are, using sealing wax to seal adjustment screws, Putting a lead seal on the parts that could be tampered etc.

All measuring equipment should be handled and stored so as not to cause any damage to them. They should be protected from extremes of conditions like temperature, humidity, vibration, dust etc. Equipment should also be maintained regularly as appropriate.

Detailed records of all calibration activity should be maintained. The extent of information to be recorded may vary from equipment to equipment, but as a guideline, recording of the following information will be useful:

a) Description/Identification of equipment;
b) Date of introduction of equipment for use;
c) Date of calibration;
d) Results of calibration;
e) Permissible limits of error;
f) Calibration interval/next date of calibration;
g) Reference to calibration procedure;
h) Master equipment used for calibration;
j) Environmental conditions;
k) Details of any repairs, adjustments etc, carried out; and
m) Any limitations of use.

The validity of previous inspection records should be assessed when any equipment is found out of calibration. When such a situation occurs, the following action should be taken:

a) Examine the records of last calibration and if possible, revalidate the same.
b) Confirm that the inaccuracy has occurred only after the latest calibration.

c) Where possible re-check the product and/or service features measured with the out of calibration equipment. If any product and/or service is found to be out of limits then immediate action should be taken to isolate all such nonconforming products and/or services.
d) Assess the possible effects of the nonconformance on the final quality of the product and/or service.
e) Reappraise the frequency of calibration for this particular equipment.

Some measuring equipment may use software for its operation and in the calibration process. In such cases the software may have to be validated to ensure it can carry out the required measurements accurately. Normally manufacturers provide the validation method. If not provided a known accurate product (a standard gauge block or product with known parameters) can be used to check the accuracy of the software. For in-house calibration, the reference standard used will need to be calibrated from an external source authorized to calibrate such reference standards (for example, National Physical Laboratory).

If an external agency is used for calibration, the following points should be considered:

a) The external agency should be endorsed or authorized for carrying out calibration services by a suitable accreditation body.
b) The agency should issue a certificate of calibration giving all details and also indicating the measurement uncertainty.
c) The reference standard used for calibration should be indicated along with details of calibration of the standard.

Calibration is an expensive process and therefore, it is important that calibration agency is identified properly.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of the product,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

What Does This Mean?

The requirement for monitoring, measurement, analysis and improvement processes to be planned means that these processes should not be left to chance. It is obvious that measurements made without a target value are measurements without a purpose. Target should always be focused on so that, there is sound relationship between targets, measures and objectives of the organization.

It is necessary to plan how the monitoring and measuring activities are to be carried out and how these are to be used. The processes to which these will be applied include:

a) *Processes needed to demonstrate conformity of the product and/or service*

   This would cover monitoring and measurement of processes (**8.2.3**), monitoring and measurement of product (**8.2.4**), verification of the purchased product (**7.4.3**) and control of nonconforming product (**8.3**).

b) *Processes needed to ensure conformity of the quality management system*

   This would cover 'Customer Satisfaction' (**8.2.1**) and 'Internal Audit' (**8.2.2**).

c) *Processes needed to continually improve effectiveness of quality management system*

   This would cover 'Data Analysis' (**8.4**), 'Continual Improvement' (**8.5.1**), 'Corrective Action' (**8.5.2**), 'Preventive Action' (**8.5.3**) and 'Management Review' (**5.6**).

While planning the above processes, the methods of monitoring, measurement, analysis and improvements should be defined including use of statistical techniques. Some of the problem solving statistical techniques which could be used are Cause and effect diagram, Pareto diagram, Check sheet, Histograms, Stratification, Correlation and regression, Control charts, Matrix analysis etc. For more details reference may be made to IS 14978 : 2002 'New seven tools for quality management' and IS 15431 : 2003 'Seven tools for quality management'.

8.2 Monitoring and Measurement

8.2.1 *Customer Satisfaction*

> As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

What Does This Mean?

IS/ISO 9001 places a great emphasis on achieving customer satisfaction. The first relation with the customers starts through understanding their needs and expectations (both stated and unstated). It is must that products and/or services that are offered meet every need of the customer, as it would go a long way in meeting expectations of the customer. Some customers might complain if their requirements are not met while those who do not complain may switch to others.

'Satisfaction' from the products and/or services is the 'right' of the customer and therefore 'satisfaction' generally produces a neutral response from the customer. 'Dissatisfaction' may generate a variety of emotions and most common may be 'not to buy again'. The opposite of 'dissatisfaction' is the 'surprise' or 'delight' where customer's expectations are truly exceeded.

For complying with above requirement of IS/ISO 9001, an organization should ensure, by using suitable method(s), that:

a) systematic checks on a periodic or continuous basis are carried out to obtain the information/data on customer perception relating to products and/or services supplied to him,
b) the above data is analyzed to check as to what was promised to the customer has been provided or not, and
c) The result of analysis (preferably quantifiable) is being used for evaluating the performance of the quality management system and for continual improvement.

It is not sufficient to only monitor the customer perception of the immediate customer in supply chain but also go further and monitor perception of others on the supply chain. For example; for a manufacturing organizations, its customers may include wholesalers, retailers, and end users. Thus there are three or more different types of customers and their requirements may be different. For an organization to be successful, it has to satisfy all of them and therefore should measure their perception.

How to Implement

There are several ways of finding out what the customers think of an organization, for example:

a) After delivery of product and/or service make telephone calls to the customers or it could be done periodically with regular customers,
b) Use suitable questionnaires to obtain customer feedback,
c) Interview some customers by using a prepared checklist,
d) Other contacts (meetings, e-mail, etc) with customers,
e) Verbal feedbacks or compliments received by the personnel who are in contact with the customers, and
f) Attrition interviews (reasons for leaving).

In addition, there are other information already available with the organization, which when analyzed will give an indication of customer satisfaction, for example:

a) Number of repeat orders received from the same customer,
b) Number of years customer(s) stayed,
c) Monitoring the movement of customers to and from the competitors,
d) New customers referred by old customers,

e) Monitoring the demand for the products and/or services relative to the estimated demand,
f) Trends of customer complaints that is upward or downward trend,
g) Monitoring accounts receivables from customers,
h) Monitoring warranty claims, and
j) Media reports about the organization.

All the above have their merits and demerits. It is advisable to start with simple one like calling right person in the customer's organizations on telephone for feedback or meeting an individual customer after service has been provided, for example, meeting and obtaining feedback from a checking out customer in a hotel/restaurant/airline/bank branch etc, depending upon the kind of product and/or service provided.

Where this technique is not feasible, survey/questionnaire method may be used. Surveys and questionnaire are time consuming, expensive and their response rate is low. It is advisable to keep questionnaire simple and easy to answer. Always test the questionnaire with few customers before it is sent.

It is expected that by obtaining and analysing information from the customers and by analyzing already available information, it would be possible to make out whether quality management system is effective or not. Needless to mention that 'customer' is the 'final auditor' of the system and his assessment should be honoured and acted upon in such a manner that higher and higher patronage is received from customers.

Examples

In the service industry like hotels, restaurants, airlines, railways, catering and training activities, it is quite common to obtain feedback from the customers immediately after service is completed in a pre-designed questionnaire. Number of questions in the feedback form would vary depending upon the type of service provided, for example, in hotel industry it may cover feedback on check in, room service, restaurant service, travel arrangements, parking of vehicles, baggage handling, bill preparation, check out etc. It is recommended that the questioners should be small and simple.

In case of consumer products and consumer durable products etc, the customer surveys have been most popular and specialized agencies are available for conducting scientific surveys.

In case of ancillary industry a direct contact with the customer at the right level is the recommended.

An example of data gathering sheet for collecting results of survey of 10 customers conducted at a retail outlet selling the products is given in Table 1.

Table 1 Data Gathering Sheet

Question	Respondents									
	1	2	3	4	5	6	7	8	9	10
Our product/service performs as expected	*									
Our products are suitably packaged										
You receive sufficient information about our products/services										
Our products give good value for money										
You would recommend our products to your friends										
Any comments/suggestions on the product and/or service or the organization. 1. 2. 3.										

* The response of the customers will be recorded here by giving following scores.

5 — Agree strongly
4 — Agree
3 — No opinion
2 — Disagree
1 — Disagree strongly

For further guidance on Measurement of Customer Satisfaction (*see* IS 15610).

8.2.2 *Internal Audit*

The organization shall conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 : 2002 for guidance.

What Does This Mean?

Internal audit is a process through which management can get information as to how the quality management system is functioning.

Internal audits should be conducted periodically. There may be variations in the frequency of audits of different departments. For example, the frequency of internal audits may be more for such departments, which have direct links with customers, or to whom higher number of customer complaints has been attributed or where previous audit results show larger nonconformities. While for other departments frequency of audits could be less. Not withstanding this, each department should be audited at a fixed interval, say, once in 3 or 6 months.

During internal audit following are assessed:

a) Is every thing happening as planned, for example, check achievement of quality objectives, quality plans, product and/or service conformity etc?
b) Are all the quality management system requirements of IS/ISO 9001 being met effectively?
c) Are all the quality management system requirements as stated by the organization in its quality manual and other documents being met effectively?

The person responsible for managing audit function should develop annual audit programme and for each audit cycle an audit schedule covering basis of audit (criteria), scope (activities to be audited), audit dates and duration, audit team leader and member etc should be prepared in advance and communicated to the audit team leader and the departments to be audited.

It is necessary that trained internal auditors are deputed for auditing in such a manner that the activities they are assigned to audit are not those for which they, or to whom they report, are directly responsible. This will ensure objectivity during audit and also avoid 'bias' if any.

After completion of the audit, which is conducted by obtaining evidences (through examination of records, observation of activities, questioning/interviewing people etc), the auditors compare the same with audit criteria (policies, objectives, procedures, requirements from customer, IS/ISO 9001 requirements etc) and prepare their audit findings in terms of 'conformities' and 'nonconformities'. These nonconformities should be firstly discussed by the auditee, then prepared and conveyed to the auditee during audit itself. The auditee should take following two actions within agreed time frame on each of nonconformity reported:

a) The nonconformity is corrected that is action is taken to eliminate the nonconformity, and
b) The cause of nonconformity is investigated and removed in such a manner that possibility of similar nonconformity happening in future is eliminated that is taking 'corrective action'. The possible system related root-causes of nonconformity could be:

1) Inadequate training;
2) Incapable processes;
3) Not following procedures;
4) Instructions/information not clear;
5) Poor maintenance;
6) Poor planning;
7) Poor work environment;
8) Supplier quality problem; and
9) Improper process steps, etc.

After the 'correction' and 'corrective action' as stated above have been completed by the departmental head, the person responsible for the audit management in the organization will arrange to check if actions have been satisfactorily completed. This could either be done by obtaining written confirmation from the concerned departments and verifying the same during next cycle of audit or a special internal audits (called follow up audit) be arranged to verify the action and outcome of these verifications should be recorded and reported to the concerned departments.

It is necessary to develop a written procedure covering all the above audit steps and also indicating responsibilities for:

a) planning of audits,
b) conducting of audit,
c) verification of action taken,
d) reporting results of audit, and
e) maintaining records of audit.

How to Implement?

Following steps should be followed for implementation of internal audit process:

a) Train and appoint a senior person for managing the audit function, that is development of audit programme, audit schedule, training of auditors, reviewing checklists for the audit, reviewing audit findings, reviewing corrective action taken, organising follow up activities etc.
b) Develop a documented procedure for internal audit covering all the audit steps and defining responsibilities at all stages of the audit along with forms and formats to be used for planning, conducting and reporting audit results.
c) Select suitable persons in the organization to undergo training on auditing tools and techniques. It is preferable to nominate the persons to training courses accredited by Quality Council of India or and similar other bodies.
d) An experienced internal auditor or an external experienced auditor should conduct one or two rounds of internal audits along with trained auditors working as trainee auditors. This would facilitate the development of a competent audit team.
e) Periodic audits should be conducted by the cross functional teams and reports submitted to the incharge of the audit function for initiating corrective action process and follow up activities.
f) Following records for each audit cycle should be maintained as per procedure.
    1) Audit programme,
    2) Audit schedules,
    3) Checklists along with notes of the auditors,
    4) Audit reports with non conformity notes,
    5) Corrections and corrective action response from the concerned departments, and
    6) Verification reports of the corrective action taken.

Some useful hints for achieving objectives of internal audit are given below:

a) Involvement of top management in the audit process is necessary for its success. For this purpose top management should ensure that
    1) a senior person is assigned to manage the audit function.

2) team of internal auditors should be selected in such a manner that they can effectively audit persons at different level in the organization, for example, a junior person may not effectively interview a senior manager because of level differences.
3) auditors should be spared from the routine work for planning (preparation of checklist etc), conducting (going round all the allocated departments) and reporting the audit findings.
4) conveying to all concerned that a 'non-compliance' found during audit will not result into any type of sanction (adverse action) against the person being audited and that the audit should be regarded as a service provided to people to help them identify deficiencies in their own controls that they may have missed by being too close to the action.

b) One of the permanent objectives for each auditor should be to find out opportunities for improvement in addition to highlighting non-compliances.

c) Since requirements of IS/ISO 9001 are generic and applicable to all types of organizations therefore it is not good to use during audit model checklists available in some books. It is much more effective to translate the requirements of IS/ISO 9001 into a checklist of audit questions that are specific to the area and activity being audited and as applicable to the organization.

d) Ideally auditors should not audit their own work but in small organizations it may not be possible to have total independence. In such cases it is necessary to be able to show that audit was carried out as objectively as possible, for example, by using specific checklist during the audit. In some cases consultants who are providing auditing services can also be used for conducting impartial internal audits.

For further guidance, see IS/ISO 19011.

A typical quality management system internal audit procedure along with the specimen forms is given in Annex D for guidance.

8.2.3 *Monitoring and Measurement of Processes*

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

What Does This Mean?

It may always not be possible to determine the quality of the final product and/or service only on the basis of inspection or testing of the product and/or service. Therefore it is necessary to find out that the process itself has been operating at all times under the controlled conditions. It is necessary to periodically monitor and/or measure processes to check if they are delivering desired results. This requirement of monitoring and measurement of processes is not only applicable for production processes and service provision processes but for all other processes as identified for quality management system, such as,

a) Sales process,
b) Purchasing process,
c) Storage process,
d) Delivery process,
e) Complaint handling process,
f) Calibration process,
g) Machine maintenance process,
h) Training process,
j) Document control process,
k) Record control process,
m) Management review process, and
n) Internal audit process.

The key word in this requirement is 'planned results'. Every process is designed to achieve some results which are performance requirements of the process as fixed by the management, for example, 'Key Performance

Indicators' (KPI) or 'Performance Measures' of the process, which could be termed as planned results of the process under monitoring.

This clause requires:

a) Each of the quality management system processes should be monitored by using suitable method (s).
b) Wherever applicable, the processes should also be measured.
c) Methods used for monitoring and/or measurement should demonstrate that the processes have achieved the planned results.
d) After monitoring and/or measurement if it is found that planned results are not achieved, action should be taken to correct the process appropriately so that planned results are achieved.
e) In addition to action at (d) above, the "cause" of the process not being able to achieve planned results should also be identified and appropriate action taken to eliminate the cause of inability of the process to achieve planned results so that process continues to achieve planned results.

How to Implement?

Monitoring and measurement of a process could be detailed in a number of ways, such as:

a) As desired in the customer's order,
b) An instruction or procedure for monitoring of the process,
c) An inspection and test plan of the process,
d) A checklist prepared for monitoring the process, and
e) A quality plan.

Monitoring and measurement of processes is generally performed by the process owners (managers). These owners should be able to find the following after monitoring the processes:

a) Is the process performing as planned?
b) Is the process achieving the results in the best way?
c) Are the results being achieved are those necessary to fulfil organization's goals?

In addition to monitoring the processes as contained in the documents mentioned above, it will be necessary to establish objectives for each process and targets should be fixed keeping in view the ability of the process to deliver the desired results.

When a process control parameter is found to be drifting away from the target, correction as well as corrective action should be taken to eliminate the cause(s) of the nonconformity.

Examples

Followings are some examples of performance measures for the processes:

Process	*Activities for Monitoring and/or Measurement*
Sales and Marketing	– Average time for response to customer enquiries. – Percent of correctly prepared quotations. – Percent of enquiries converted to customer orders. – Percent of customer orders accepted without changes to terms offered in quotations. – Average time for response to amendments made in customer's orders. – Percent of correct execution of customer orders including delivery commitments. – Percent of times concessions obtained on supplies made to the customers. – Average response time to customer complaints.
Purchasing	– Percent of correctly prepared purchase orders including product and/or service requirements. – Percent of times suppliers asked for clarifications on the purchase orders. – Percent of times the materials from suppliers were received as stipulated in purchase orders. – Percent of times production processes were held up due to material received was not meeting the requirements or delay in receipt.

Storage	– Number of times wrong issuance of material. – Number of times material was not available due to lack of planning by stores. – Any deviation in storage temperature, humidity and other storage requirements like stack heights, maximum quantities allowed for storage. – Percent of times there is deviation in the physical quality available in stores *vis-à-vis* that as per the register.
Maintenance	– Percentage of online availability of working machines. – Adherence to preventive maintenance schedules. – Average time between two breakdowns of the same machine. – Cost of maintenance of machines.
Training	– Percent of training programmes organized on same subject to that planned as per schedule in a month/year. – Percent of actual average training man-days of employees to the planned training man-days. – Effectiveness of training as feedback received from user departments or test conducted.
Document Control	– Instances of unauthorized changes to controlled documents. – Instances of superseded documents (both internal and external) in use; etc.
Record Control	– Instances of records not available. – Instances of records not legible.
Production and/or Service Provision Processes	– Time control – Temperature control – Pressure control – Humidity control – Viscosity control – Cycle time control – Waiting time control – Accuracy of processing transaction – Defined process parameter controls – Number of items produced

8.2.4 *Monitoring and Measurement of Product*

> The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).
>
> Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).
>
> Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

What Does This Mean?

In addition to the monitoring and measurement of processes as given in **8.2.3** it is necessary to check the product and/or service quality at various stages of production or service provision. The extent of such product and/or service inspection would depend upon the level of controls exercised over the processes. During such inspections, various characteristics of the product viz. dimensions, workmanship, hardness, tensile strength, chemical composition etc, in case of manufactured products, and accuracy of transaction, response time to customer queries, proof reading, taste of the food, placement of crockery and other items on a dinning table in a restaurant etc, in case of service provision, would need to be monitored and measured at various stages of product and service realization. Generally such inspection and testing are conducted at following stages:

a) Incoming stage,

b) In-process stages, and
c) Final stage.

For ensuring that all required characteristics of the product and/or service are checked, it is necessary to draw up a product and/or service quality showing:

a) characteristics with its specification to be checked at each step;
b) test method and test equipment, if any, to be used;
c) persons responsible for inspection/testing;
d) action to be taken in the event of nonconformity; and
e) method of recording the inspection and testing results.

There is need to have a system of keeping the necessary monitoring and measurement records or have other means of showing that inspections have taken place. It is necessary to have a clear procedure for release of product and/or service either to next stage or for final despatch to customer. Product and/or service release should have evidence that the release has been made by the authorized person.

It is necessary to ensure that release of product and/or service to next stage of production or before despatch to customer, all necessary inspection and testing have been completed as described in the test plan mentioned above. In the event of any departure from this test plan, necessary approval for such departure should be obtained from the person within the organization who has authority to approve such deviations or from customer, provided such condition exists in the contract with the customer.

How to Implement?

Following detailed information for various stages of inspection may be provided for facilitating implementation of the above requirement:

General

Inspection and testing activity is normally included in the quality plan. The extent of planning will depend on the type of product and/or service being produced.

The following points should be kept in mind when preparing quality plan:

a) Documents required;
b) Product and/or service or contract to which the plan apply should be identified;
c) Various stages of production to be inspected/tested;
d) Personnel who will carry out inspection and testing;
e) Characteristics to be inspected;
f) Measuring equipment to be used including its class, least count;
g) Sampling plan for inspection and testing at various stages including criteria for acceptance; and
h) Kind of information to be recorded and systems for maintaining records.

Although it is expected that inspection and testing will be carried out by inspection personnel, verification activities may be carried out by the operators themselves provided they have been trained for it and are authorized to do so. However, when operators have been authorized to inspect the items, it is necessary to ensure that the operators have all the resources available for carrying out the verification activity.

In planning for inspection, a balance will have to be struck between various activities like supply source inspection (at supplier's end, wherever relevant), receiving inspection, in-process inspection, final inspection, etc. The level of activities will depend on the kind of quality the customer is expecting and the resources available with the organizations.

Receiving Inspection and Testing

There are many ways of ensuring the quality of products and/or services received from suppliers. In general, it is better to carry out as close to the source of production as possible so as to reduce the possibility of nonconforming products and/or services being procured. Receiving inspection activities should not duplicate the inspection activities being carried out at the source of production but should be complementary to it. Records are an important part of inspection activities. These records should also include all material test certificates and inspection reports which need to be given by the suppliers. The quality system should ensure that the material is not released for production and quarantined till all necessary certificates have been received and all the inspections have been carried out.

In case of discrete items to be procured, sampling plans may be used to verify the quality of material, for which help may be taken from IS 2500 (Part 1)/ISO 2589-1 and IS 2500 (Part 2).

If it becomes necessary to release the material for production due to urgent requirements then it can only be done with the approval of authorized person and steps should be taken to positively identify the same so that the finished product can be traced and recalled, if necessary, at a later date/stage.

In-process Inspection and Testing

Similar to receiving inspection, detailed quality plan may be prepared for in-process inspection also. The quantum of inspection/test and the frequency should be sufficient to provide confidence that the product and/or service at in-process stages meet specified requirements.

When the product is a complex one, involving a number of operations, the activities are many and therefore, these activities have to be planned properly to ensure that inspection activities run concurrently with the production process.

Records of these should be maintained as evidence that inspection and testing has been carried out. The inspection activities should be supplementary to the process control activities that may be in place. If any hold points have been specified by the customer then suitable provision should be made in the system to ensure that the production does not proceed beyond this point and customer is notified accordingly.

Final Inspection and Testing

Final inspection is the activity which is carried out to determine a product's overall compliance with the specified requirements. For this, it is necessary to ensure that all receiving inspection, process, control checks and in-process inspections have been carried out and records are available to prove that the results of these checks are satisfactory. This will help to complete the final inspection process quickly and all necessary data will be available for verification at the final inspection stage. When various components or sub-assemblies are being assembled into a larger product then it is imperative that each of these components or sub-assemblies is treated as a final product since they may not be accessible for inspection separately after assembly. The stages, where components start getting assembled into sub-assemblies or final assembly, can be treated as hold points to ensure that these items are checked properly before clearing for assembly. These hold points are independent of customer's hold points.

The quality management system should ensure that a product does not get despatched until all activities specified in the quality plan are completed. Further the system must be able to collect all the results of activities affecting quality so that they can be reviewed immediately after production of final product is complete. Whenever a deficiency in the product and/or service is noticed, the quality assurance department should have the freedom and authority to discuss the same with the concerned person/department and resolve it to the satisfaction of all. But on no account should any deficient product and/or service be dispatched without the explicit permission of the customer.

Inspection and Test Records

These records are essential to demonstrate to the purchaser that not only the product and/or service quality been achieved but has also been maintained at various stages of production.

The type of records will vary from product to product and operation to operation. However, the record should contain all the essential data required for ensuring product and/or service quality. Some guidelines are given below on the kind of information to be recorded on inspection reports:

a) Component, sub-assembly or product and/or service inspected;
b) Characteristics inspected;
c) Reference inspection procedure sheets;
d) Reference standard (Company Standard, National Standard, International Standard, etc);
e) Results of the inspection or testing;
f) Decision (whether accepted or rejected);
g) Name and designation of the persons who carried out the inspection;

h) Authority for final acceptance (if other than inspector);
j) Date on which inspection was carried out; and
k) Any other information used during inspection/evaluation.

8.3 Control of Nonconforming Product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected non-conformity;
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the non-conformity.

What Does This Mean?

Non-fulfillment of a specified requirement is termed as nonconformity. This may occur in a product and/or service, anywhere during the product and/or service realization process. It is, therefore, essential for an organization to ensure that such nonconforming product and/or service is not used or dispatched to the next stage. This is also applicable in a multi-stage process where the next stage is a customer to the previous stage.

It is essential for the organization to identify the nonconforming product and/or service and segregate it from other conforming products and/or services to ensure there is no mix up, to prevent its unintended use.

It is essential to have a document describing the procedure for dealing with nonconforming product and/or service along with the responsibilities and authority for its disposal. There are various ways through which the nonconforming products and/or services can be dealt with, namely,

a) by taking up repair or rework to make the product and/or service conforming to specifications. Re-verification of the correction on the product and/or service should be carried out to demonstrate conformity.
b) acceptance after analysis of the implications of the observed nonconformity by designated authority and in consultation with customer, wherever applicable.
c) regarding the product and/or service to another application based on its suitability of use.
d) Scrapping of the nonconforming product and/or service.

Records of the nature of nonconformities and actions taken thereafter should be maintained. The feedback of nonconformity detected after product and/or service delivery or use should be utilized for taking appropriate corrective and/or preventive action.

How to Implement?

It is essential to have a documented procedure of how control of nonconforming product and/or service need to be performed. The procedure should cover all aspects such as identification, documentation, segregation, evaluation and disposal of such a product and/or service. The details of the nonconforming product and/or service, for example, name of the item, location and nature of the nonconformity needs to be recorded to ensure traceability at later stage.

As soon as a nonconformance occurs, the product and/or service is to be clearly identified by a suitable code or mark so that identification is apparent. It may be ensured that such marking is indelible.

The documentation consists recording the occurrence of nonconforming product and/or service through a report giving various details as above. The report also contains details of review of the nonconformity, and its suggested disposal as well as steps to prevent its recurrence.

The nonconforming product and/or service should be segregated to a designated place till such time a final decision is taken for its disposal.

The review of the nonconformity is to be carried out by a designated person based on the implication of the observed nonconformity on the intended use of the product and/or service. Some customers might require notification of any nonconforming product and/or service and approve what should be taken. In such cases it will be necessary to notify and take consent of the customer.

As explained above, there could be alternate ways of disposal of nonconforming products and/or services. The examples for different situations can include:

Rework — *Examples*

a) A 16 mm hole was drilled in a steel plate against a specification of 20 mm. The item can be reworked to enlarge the hole to 20 mm for conformity.

b) A formulation was found to contain less technical content than that was required by the specification. The same can be reformulated to bring the technical content to the specification.

Repair — *Example*

An electric storage water heater was failing in performance test. This could be repaired by replacing the defective parts.

Acceptance with Deviation

By accepting the nonconforming product and/or service, as a deviation or a concession to the specification, if it is assessed after review, that the performance of the product and/or service would not be effected because of the nonconformance. Alternatively, by using the product and/or service for an application other than the original intended application.

Examples

A fan when fabricated may have a flange dimension slightly bigger. The review may indicate that if the flange holes can be matched without problem the nonconformance may be accepted.

A precision meter with the accuracy level is ± 2 percent may be nonconforming when specified accuracy level is ± 1 percent. However, these meters can be released in the market for applications where specified accuracy ± 2 percent.

In the event the delivery of the product and/or service has been affected to the customers before the nonconformity is detected, the effect of such nonconformity on the usage of the product and/or service by the customer should be reviewed and depending on the severity of the impact, suitable action needs to be initiated by the organization.

Example

A shaft to be used in a rotating machine has to be heat treated to a certain temperature. However, after the delivery of the shaft, if it is detected that the temperature was below the requirements, then it has to be investigated in-house whether with this changed conditions, whether the shaft is still acceptable, and if not, customer should be asked to check the application details of the shaft and if unsuitable, should be asked to return the same.

In case of situation involving service industry, the nonconformity becomes apparent only after the service has been rendered. In such situation, it is not always possible to take corrective action in the same manner in which it can be taken for products, for example, late delivery of documents by the courier service cannot be rectified, but only corrective action can be taken. Similarly, if the person falls sick due to food poisoning, only corrective action could be taken by him to prevent its re-occurrence.

8.4 Analysis of Data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 7.2.1),
c) characteristics and trends of processes and products including opportunities for preventive action, and
d) suppliers.

What Does This Mean?

For identifying opportunities of improvement in quality management system, processes, products and/or services, it is necessary that the data gathered during measurement of various processes and products and/or services are analysed in a systematic manner. Collecting, summarizing and analysing and evaluating the data enables in taking fact-based decisions.

When data is analysed and evaluated, it can indicate already changed or changing and emerging trends. They provide pointers to:

a) existing or potential problems,
b) possible factors and causes for the same in order to develop solution choices for collective and preventive action, and
c) changes needed in the quality management system.

IS/ISO 9001 requires analysis of data in the following areas:

a) Level of satisfaction amongst customers,
b) Extent to which conformity to product and/or service to the specified requirements is being achieved,
c) Trends of key characteristics of the processes,
d) Trends of key characteristics of the product and/or service,
e) Trends of deliverables by the suppliers, and
f) Opportunities for preventive action based upon the above data.

How to Implement?

Data Collection

Normally a data collection should include:

a) **What** data to be collected,
b) From **Where** the data to be collected,
c) **When** (frequency) data will be collected,
d) **Why** (purpose) data is to be collected,
e) **Who** (responsibility) will collect the data, and
f) **How** (method) is the data to be collected.

The example for each of the above is given as under:

a) **What** – Temperature of dip solution (used for dipping tyre cord fabric),
b) **Where** – From the dip solution tank at dip unit number one,
c) **When** – Every one-hour interval, starting from 06.00 hours (6 AM), from coming Monday morning for 24 hours,
d) **Why** – To find out variation if any, in the temperature (to correct to dip pick-up),
e) **Who** – Shift operators in respective shift, and

f) **How** – Read temperature to the nearest 0.5 degree centigrade, from the thermometer fixed in the tank.

NOTES

1 Readings should be taken within plus/minus 5 minutes to the hour,

2 To record temperature in the check sheet provided, and

3 Record anything unusual which can affect the data collection process and purpose (for example, stoppage of the unit; if so, then what time to what time).

For this purpose, a suitable proforma should be developed.

Quantitative, objective measurements are preferred since they are based on facts. It is useful to remember that information can be obtained by:

a) measuring variables (say, temperature, pressure) through appropriate devices and instruments;
b) counting attributes (number of incidence of say, defects); and
c) observing, using the senses (colour stain, contrast, uneven surface etc). However qualitative measurements such as observations, opinions, feelings and intuition that are subjective also form part of the decision-making process. It is preferred that a relevant quantitative data analysis is also done along with qualitative information for decisions.

Some examples of sources of data collection would include:

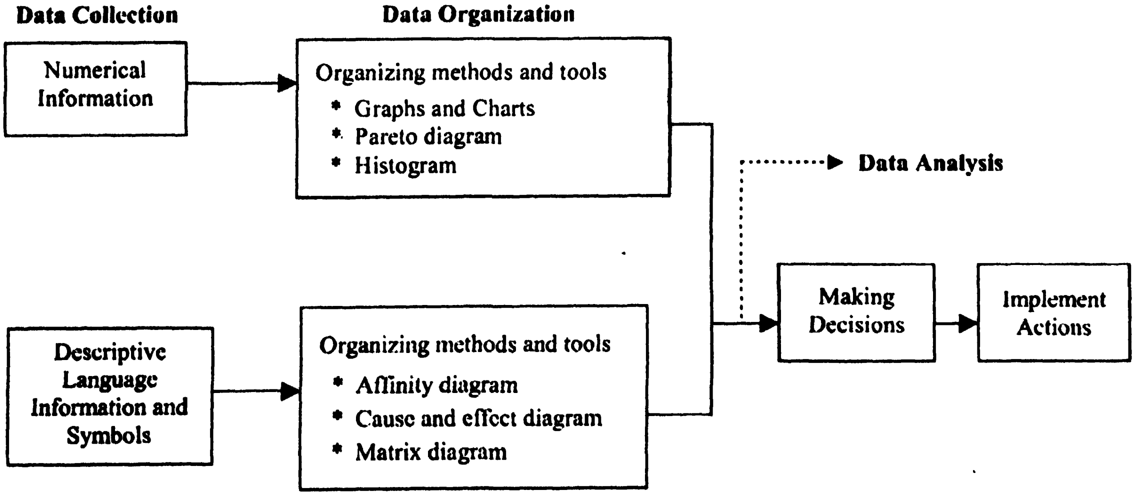
a) Customer complaint,
b) Machine downtime,
c) Missed delivery dates,
d) Response time,
e) Customer queries,
f) Internal information,
g) Product and/or service testing,
h) Rejection, rework and scrap,
j) Process deviation,
k) Internal audit nonconformities,
m) Training feedback, and
n) Document and/or records not under control.

An organization is usually structured on the lines of functions, levels or layers and locations etc, with the people responsible for various activities. The business and organizational processes do not necessarily follow above structure. Hence there is a need for gathering data for analysis purposes from all parts of the organization to assess performance and communicate in an appropriate way, for people to take decisions and act upon them.

Data Organization

It is always helpful to use appropriate methods and analytical tools and techniques for organizing the data in an easy to understand manner to enable decision-making and implementation.

To illustrate:



This is only given as illustrative example and is not the only method or tool available for data organization.

Data Analysis

Data analysis is to be done both on 'result measures' and 'process measures'. For example, 'customer satisfaction' and 'customer dissatisfaction' are result measures whereas 'customer complaints redressal time' would be a process performance measure.

Education and training of people on use of appropriate methods and tools are important. Softwares are also available to do data analysis and presentation. There are various tools and techniques available for data analysis. Annex H may be referred for examples of statistical techniques relating to certain functional areas.

Benefits of Data Analysis

Data analysis helps in assessing the performance and identifying areas for improvement. Analysis of data, when properly carried out provides opportunities for measuring performance improvement on following:

a) To compare present trend with the past trend or compare the present trend with the prescribed standard. For example, a supplier's materials rejection in percentage or ppm against past percentage or ppm or organization's specified limits.

b) To compare customer's perception against fulfillment of expectations. May be by a survey data analysis or analysing claims data.

c) To compare organization's performance against the best competitor on any aspects.

d) To compare current with the possible ultimate performance level (like 6σ level).

For further guidance, *see* IS 7200 (Part 1) and IS 7200 (Part 2).

8.5 Improvement

8.5.1 *Continual Improvement*

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

What Does This Mean?

IS/ISO 9001 suggests the following for continual improvement:

a) Providing direction to the organization by stating continual improvement as a policy of the organization.

b) Periodic review of the quality objectives in setting higher targets for achievements.

c) Each internal audit bringing out opportunities for improvement in the processes.

d) Improvement projects identified by using results of data analysis.

e) Eliminating root causes of the nonconformities in the products and/or services, processes and systems to avoid their repetitions, thus leading to improvement in the product and/or service conformity, process conformity and system conformity.

f) Identifying potential nonconformities from the past trend of processes or from the market survey or competitors data for initiating preventive action to avoid occurrence of such problem in the organization.

g) The permanent outcome of each management review should be to identify improvement in the product and/or service requirements as well as process improvement including commitment of the management to provide resources for such improvement.

How to Implement?

Examples of some of the areas where quality management system can be improved include:

a) Communication to customers on products and/or services information,

b) Customer queries and complaints handling,

c) Customers' stated and un-stated requirements and organization's ability to meet them,

d) Interfaces between different internal groups or functions involved in design and development of products and/or services,
e) Suppliers evaluation and purchasing process,
f) Effectiveness of management review meetings, and
g) Developing competence and skills of people to perform various tasks.

Organizations, especially management should identify the sources of information for improvement objectives and opportunities. Examples of some of the sources for information and data include:

a) Warranty claims and compensation;
b) All reported nonconformities;
c) Repair, rework, down grading;
d) Calibration and measurement errors;
e) All audit reports;
f) Accident reports;
g) Contract reviews;
h) Products and/or services and markets — segment-wise sales trends;
j) Equipments effective utilization; and
k) Outputs from data analysis.

Continual improvement can be approached in two ways. In the first approach, the improvements are step-by-step and incremental in nature, the activities are focused primarily on improving existing processes. In the second approach, the improvements are in the nature of break through, to attain a new level of performance or results. That can lead to revision/re-design of prevailing process or implementation of a new process. Both approaches may be used in an organization.

Continual improvement calls for creating an organizational environment and culture in which all employees, individually and in teams involve themselves to seek and solve problems by way of corrective action and contribute to preventive action.

Management should provide them with required authority, support and necessary resources to implement the changes associated with improvements. Some kind of structured mechanisms may be actively promoted by the management for both step-by-step and break through improvements. There could be suggestion schemes, small group activities, cross functional project teams (with persons from appropriate function/disciplines related to the problem or potential problem). Management should promote education and training of employees to learn and apply relevant processes, tools and techniques (such as problem solving process, root cause analysis and decisions matrices for solutions) for continual improvement. Suitable methods for recognizing and rewarding concerned people for their contribution and results may be implemented.

The two processes for continual improvement, which can easily be adopted by an organization, are corrective action and preventive action. In the corrective action process, the prevailing problems are identified, prioritized and the resources are assigned to tackle them systematically, reaching the root causes and implementing appropriate solutions so they do not occur again.

In the preventive action process, the potential problems and opportunities for improvements are identified and evaluated systematically and in proportion to the risk or benefit, resources are deployed to implement needed actions so that the problem does not occur at all.

8.5.2 *Corrective Action*

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for:

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken (see 4.2.4), and
f) reviewing corrective action taken.

What Does This Mean?

When a nonconformity or a problem occurs in the process or product and/or service or quality management system, the systematic measures should be taken to find and implement solution that eliminates recurrence of problem, and this is defined as corrective action in IS/ISO 9001. The objective is to eliminate the causes and consequent unfavourable effects of a problem or a nonconformity.

IS/ISO 9001 requires to have a documented procedure for corrective action, which includes:

a) reviewing customer complaints and other existing nonconformities,
b) finding out the causes and root causes,
c) deciding on the needed solutions, which are appropriate to the effects of the nonconformity,
d) implementing the chosen solution,
e) verifying if the chosen solution is effective. If yes, record corrective action. If no, find out other causes not considered earlier and then follow the same process from (c) above, and
f) making necessary modifications in the document(s), wherever required.

How to Implement?

Sometime the cause of nonconformity may be improper working methods, non-compliance to written procedures and work instructions or following a modified procedure different from the approved one.

This may call for determining whether the operation causing the difficulty can be modified to a simpler procedure or whether the operating personnel need more intensive training to carry out the process as per the approved procedure. Such analysis would require valid data and records of related activities.

Since IS/ISO 9001 calls for reviewing nonconformities, the source information, such as, customer complaints, warranty claims, rework and repair, nonconformities reports and audit reports need to be accessed. Further, the methods for collecting, analysing and communicating and sharing such information with all concerned have to be decided.

The action to be taken should be in line with the severity of the problem and the likely risks associated with not implementing any corrective action.

People from appropriate disciplines should participate in corrective action process. One has to decide on the prioritization and resources allocation based on the severity of the problem or nonconformity in product and/or service, process or quality management system, the unfavourable impact on customer satisfaction and business performance results.

One may decide to assign specific responsibility for corrective action to individuals or teams or groups to work on them and report on progress for review. A time limit may be set both for implementation of corrective action and for follow up review, within a reasonable period.

There may be a need for people assigned for corrective action projects to get appropriate training in the process and related techniques. It is important that the corrective action taken with regard to a nonconformity do not lead to unforeseen or adverse consequences in some other aspects of the product, service, or process in the organization or to the supplier or to the customer.

It may become necessary to make changes in the quality manual, procedures, work instructions or other relevant document as a result of the changes implemented as corrective action.

The corrective action taken need to relate to the changes made as above and the effectiveness in eliminating recurrence. It should be clear that corrective action process is focused on improvement on a more durable basis; it is not to be equated with actions (such as, concession, rework or repair) for control of nonconformity which is meant for avoidance of unintended use of a nonconforming product and/or service. Thus corrective action help to prevent recurrence of identified nonconformities and problems.

8.5.3 *Preventive Action*

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for:

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken (see 4.2.4), and
e) reviewing preventive action taken.

What Does This Mean?

A proactive approach to manage the organization is to find the causes of potential problems that can lead to customer dissatisfaction and take preventive action to avoid them from occurring, which otherwise can impair the business performance and results. Preventive action is an important process for improving the process, product, service or quality management system. Taking preventive action mitigates the unfavourable consequences of an emerging problem and in fact can help to improve the performance.

A documented procedure is required for preventive action, which should describe the methodology of taking and implementing preventive action and should include:

a) identifying and prioritizing potential problems,
b) carrying out investigation to find causes,
c) evaluating alternatives for choice of actions to prevent the occurrence of the problem or nonconformity,
d) implementing the action and proving its effectiveness,
e) documenting the results,
f) establishing the new method as a standard, and
g) reviewing the action taken to find out whether it continues to be effective.

For continual improvement one should look for all the opportunities for improvements, and for this, number of sources of information, as given below, have to be identified and action initiated before the potential problem becomes nonconformity:

a) checking quality system records to see if any trend exists which show that a potential problem could arise,
b) monitoring the trends in performance on various parameters, and
c) using results of data analysis.

How to Implement?

Some of the information/data sources which can be analysed for potential problems and opportunities for improvement include:

a) Customer survey results such as satisfaction measurements against expectations;
b) Analysis of sales trends: product/market/customer segment wise;
c) Service reports on concessions, warranty loss, resolution time;
d) In-process and final output reports such as final inspection failures, rejection, rework;
e) Results of audits, supplier ratings, internal processes to serve specific customer needs;
f) Outputs of various reviews like contract review and design review;
g) Data on responsiveness: increasing queue lengths, late deliveries, delayed reports; and
h) Results of statistical analysis like statistical process control charts and graphs.

Based on the criticality, an evaluation of the information and historical data for trends may be done and the potential problems may be selected and prioritized. Thereafter, develop and put in place a course of action to eliminate or reduce the risk the problem from occurring.

For this, the causes for the potential problem and their most appropriate actions have to be identified and implemented. As a result of preventive action, the quality manual, procedures, instructions and any other relevant documentation may need to be changed. Examples of, where preventive action may be applied include:

a) review of sales figures indicating customer dissatisfaction with existing level of service,
b) feedback and suggestions from employees indicating a more efficient process for deliveries,
c) safety audit report indicating actions for improving occupational health and safety practices, and

d) processes giving early warning of out of control operations through alarms and indicators, to apply mistake proofing techniques.

It is to be ensured by the management that appropriate personnel from concerned disciplines and requisite resources are made available and deployed to systematically work on preventive action process including proper implementation and review. It has to be ensured that no adverse or unanticipated effects take place in some other aspect of product or service or organization.

Both corrective and preventive action are required to be practiced by the organization for continual improvement and for increasing customer satisfaction.

ANNEX A

(*Foreword*)

STEPS FOR ESTABLISHING QUALITY MANAGEMENT SYSTEM

A-1 INTRODUCTION

There are many ways an organization can go about establishing and implementing a quality management system. This Annex provides various steps, which is one such example of establishment and implementation.

A-2 The following three stages are involved:

a) Development — Considering what happens in the organization.
b) Implementation — Putting the quality management system into operation.
c) Maintenance — Supporting and improving the quality management system.

A-2.1 Development — Considering What Happens in the Business

Step 1 Consider what are main business activities

Top management should discuss and jot down what are the main business activities and who are the customers.

It should be remembered that the idea of a quality management system is not to inhibit the academic, intellectual or creative processes involved in any of the above businesses.

It is also possible that the organization may be getting some components or service made from outside. If so, identify them and note against the relevant process areas when jotting down main business activities, as IS/ISO 9001 requires controlling of suppliers and outsourced processes.

Thereafter, establish what employees are doing. An organization chart might help in this regard. Don't forget marketing, sales, after-sales, maintenance or other personnel who might not be directly involved in core production or service activities.

Step 2 Listing activities

To achieve this next step, make a list of the main business activities.

It might help at this stage to take each of the main business activities listed originally and produce them in the form of a flowchart. Display this in office so as to attempt fast to develop a quality management system around.

The purpose of setting out business activities like this is to:

a) identify different components of business and decide if they all fit together well,

b) change something to make the whole process work better if needed, and

c) identify if the requirements of IS/ISO 9001 are covered in the business activities.

Don't make any changes yet. This is covered in step 5. Rather the idea, at this stage, is to think about the framework and structure within which the business operates and to ensure all activities are known and repeatable. This will help in consistent provision of products and/or services each time to customers.

Look at the list of main business activities already jotted down. Think if any of the activities require design work?

Design (7.3) means taking raw ideas or concepts, and through design process, develop a product or a service to suit the needs of customer.

If design or development is carried out, then the requirements of 7.3 of IS/ISO 9001 need to be addressed.

If design activity is not carried out and the manufacturing activities or service delivery is done against tried and previously developed standards or specifications, then the requirements of 7.3 of IS/ISO 9001 may be excluded (*see* **1.2**).

If design activity is being outsourced, then it is necessary to describe what controls are being exercised and they need to demonstrated (for example, using records of supplier).

Are there other activities in 7 of IS/ISO 9001, which the organization does not do? These too may be considered for exclusion as per **1.2**. Remember that anything which is being excluded must not be at the expense of the quality of product and/or service.

These exclusions have also to be justified in the quality manual (*see* **4.2.2**).

A-2.2 Implementation—Putting the Quality Management System into Operation

Step 3 Get people involved by writing down what their jobs cover

Now is the time to get everyone concerned involved in determining which of the organization's activities require documentation. This depends upon the complexity of the activity and the competency of the person performing the job. Wherever, documentation is required, it should include:

a) who is responsible for performing and checking activities?
b) where and when the activity takes place? and
c) how the activity is performed?

Some important points that need to think about are:

a) If it is a job done by a trained person or specialist, one may only refer to the type of person and the qualifications, rather than detailed descriptions of the job; for example welder, professional consultant and graphic designer.
b) Another specialized situation is in research work, where people keep notes on what they did and what the results were. It needs to be ensured that research workers make details of their work available, so that others in the organization can make use of them.
c) If, however, the work is done by casual labour, or there are specific in-house requirements, more details might be required.
d) Consider how information is passed between people. If there is a risk of this information being forgotten, misunderstood or inadvertently changed, it may be written down.
e) The sequence of the activities might still need to be defined, for example:
    1) How is the initial enquiry recorded?
    2) How is a file initiated?
    3) How does the work get started?
    4) Who monitors the progress?
    5) How is the work processed and inspected?
    6) Who decides when the work is finished?
    7) How is delivery made?
    8) What follow-up action is needed and who does it?
    9) What records are kept and who keeps them?
f) If in the organization, these details are already written down as operating or work instructions, the job is half done. Do not rewrite what is already documented. Make a note of the name and title of the document so that it can be controlled and, if necessary, referenced in other quality management system documentation at a later date.
g) Most important – Keep written documentation simple.

Step 4 Collate this in sequences relevant to the list of business activities

Once everyone has written down (or collected previously written) work instructions relevant to their part of the activity or particular job responsibilities, an authorized person (management representative) should take time out with someone else from the business:

a) to look at what has been written,

b) to satisfy that it all fits together, and

c) to deal with any gaps or inconsistencies.

Quality policy and quality objectives are to be documented and then ensure that everything that has been written is in accordance with the policy and objectives.

A senior person, who is respected by all, having an overall knowledge and analytical in approach should be appointed as a management representative.

By collating all these documents, one has a basis for documented procedures and other documentation that will be needed. If a consistent style for these documents is adopted, it will provide an opportunity to review and *improve the procedures themselves.*

Step 5 Identify where IS/ISO 9001 and this list of business activities link together

The management representative need to go through the written documents along with a copy of IS/ISO 9001 so as to find whether the requirements of IS/ISO 9001 as well as business requirements have been met.

If an area of IS/ISO 9001 has not been addressed, determine how the business covers those particular requirements. There may be a need to add some details to one of the existing procedures to ensure that the requirements are met. It may also require some additional documentation, but make sure it is relevant to the organization.

If external documents are used in business activities (such as dealers' manuals, maintenance manuals and installation manuals), it is not necessary to rewrite these to include them in the quality management system. All that is needed is to make an appropriate reference to these documents in quality manual/ procedures.

Step 6 Apply IS/ISO 9001

If others are involved in the quality management system of the organization, they are more likely to grow with the quality management system and provide useful input. The quality management system will then reflect reality rather than become irrelevant paperwork. The following points should be noted:

a) Do not create unnecessary paperwork, forms, and the like. Look at what is currently done and write down procedures or define processes to show how the job is being done. The procedure needs to be factual and not ideal. If it is found that the procedure does not reflect the way the work is done, then the procedure either needs to be revised or new one be developed. Only create a document if it is going to capture a critical activity or is going to help someone.

b) Remember, keep a record when:

   1) A good suggestion is raised, or

   2) A problem arises,

   3) A customer or employee expresses a need for action.

c) To implement the quality management system, everybody needs to have access to the documentation that relates to their activities. They need to be given some insight into how the quality management system works and why, for example, document control ensures that they have the latest copies of information relevant to their jobs and can rely on up-to-date information when making decisions.

d) Everybody needs to be trained to understand how to keep the quality management system up-to-date themselves, if changes take place in areas for which they are responsible. They also need to know how to make changes to the quality management system as well as noting problems and putting forward ideas for improvement. Remember that any changes need to be approved before they are put in place.

It is important to plan and carry out an internal audit programme and to regularly ensure the quality management system is being maintained and supported throughout the organization. It is not always easy to schedule the time required by internal auditors, but internal audits can be a most effective tool to keep everybody engaged in the quality management system and they often identify opportunities for improvement.

Keep the quality management system simple, functional and relevant to an organization operation.

The following points are worth noting:

a) The purpose of implementing a quality management system is to ensure that an organization is operating in a controlled manner and the people responsible for the various activities know and understand their roles and responsibilities.

b) Quality management system documentation should be a ready reference point to identify how, when, where and sometimes why a job should be done, or an activity managed. For that reason, the wording should be simple and in the language used in the workplace on a daily basis.

c) If job details have to be extensive or complex, then the use of a checklist could be the way to make sure that everything is done and in the correct sequence.

d) Don't forget that people also need to know what to do when things go wrong and need to have the information readily available. For example, a car owner's manual should sit in the glove box.

e) Documentation should be in a format that is easily used in the organization. For example:

   1) If computers are available, it could be easier to have a computerized system, rather than a paper system; and

   2) Where there are language or other differences in the workforce, it could be necessary to use pictures or several translations of the documents.

h) Documentation should reflect what is currently happening in an organization. During the audit process, questions will be asked and objective evidence sought to show that personnel use and understand the quality management system. This objective evidence is provided by the records and other documentation.

A-2.3 Maintenance — Supporting and Improving the Quality Management System

An effective quality management system uses feedback loops to improve how things are done in the organization, which in turn should lead to an improvement in product and/or service quality.

Step 7 Consider the feedback of implementation of quality management system to lead to improvement

By noting areas of concern from customer feedback and internal audits (Step 6), gather data or note trends that can be looked at and considered for improvement.

Improvements can be simple and easily achieved in the initial stages but could become more challenging once the obvious opportunities for improvement have been taken. It is worthwhile persevering with a systematic approach to quality improvement, since the benefits can be considerable.

Normally, improvements are adopted over a period of time as money and resources become available. A realistic approach and steady progress will build confidence and maintain enthusiasm.

Step 8 Monitor and measure the changes

It is important to remember to measure the progress. One way of doing this is to monitor mistakes and their cost. This gives one an opportunity to identify areas where cost savings could be made.

Measurements can also be obtained by noting how long or how many resources are spent on an activity or service delivery. This should always be recorded on any activity that has been chosen for improvement, prior to commencement and compared again at the end, even though the activity might be small and simple.

The various requirements of IS/ISO 9001 should combine to support the achievement of the organization's quality objectives. However, it could be useful to categorize these according to their particular relevance to different aspects of an organization, since this could influence the order in which these requirements were introduced.

ANNEX B

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

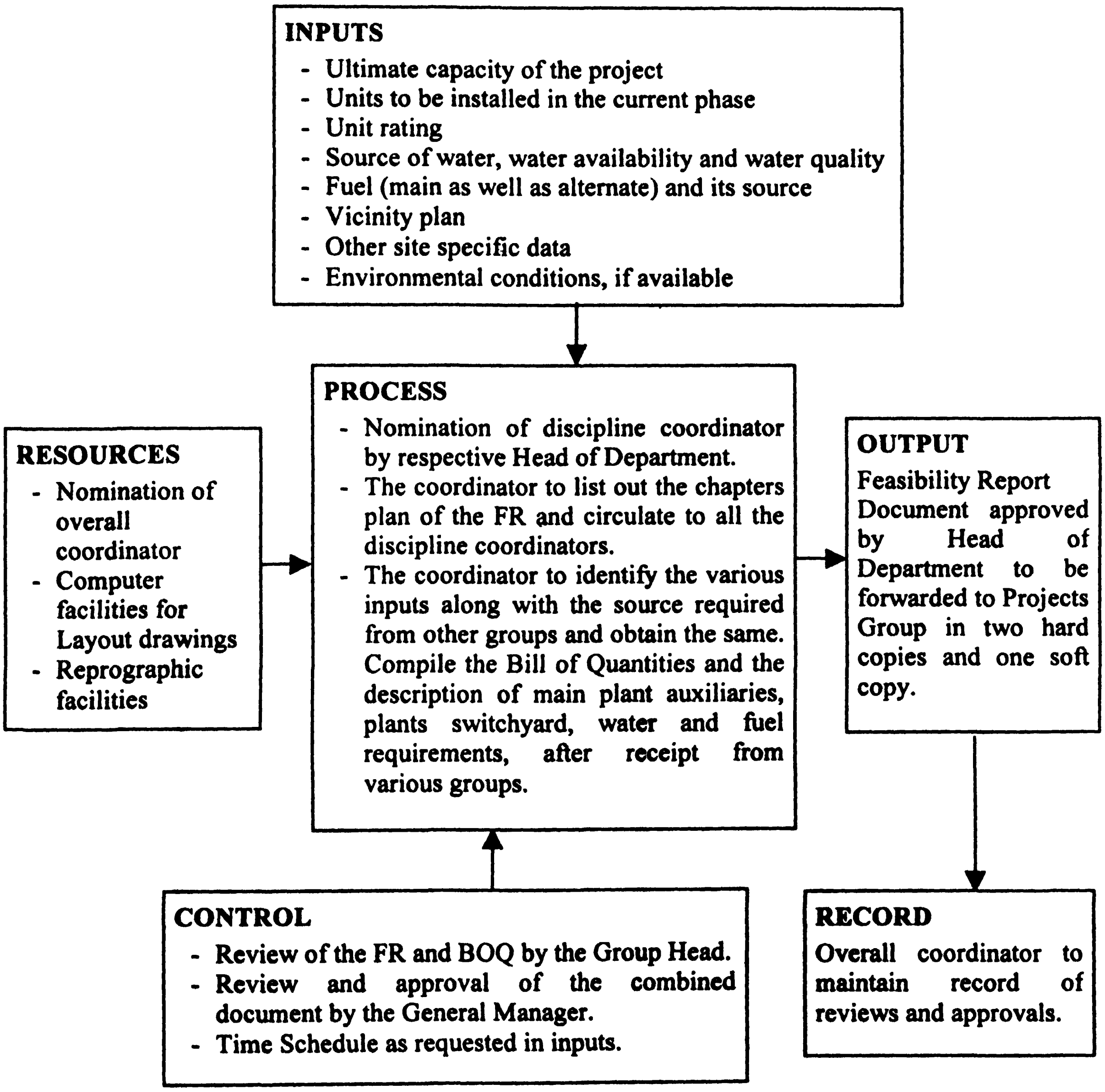
IS/ISO No.	*Title*
IS 2500 (Part 1) : 2000/ ISO 2859-1 : 1999	Sampling procedure for inspection by attributes: Part 1 Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (*third revision*)
IS 2500 (Part II) : 1965	Sampling inspection procedures: Part II Inspection by variables for percent defective
IS 7200	Presentation of statistical data:
(Part 1) : 1989	Tabulation and summarization (*second revision*)
(Part 2) : 1975	Diagrammatic representation of data
IS/ISO 9000 : 2005	Quality management system — Fundamentals and vocabulary (*third revision*)
IS/ISO 9001 : 2000	Quality management system — Requirements (*second revision*)
IS/ISO 9004 : 2000	Quality management system — Guidelines for performance improvements (*fifth revision*)
IS 15610 : 2005	Guidelines for measurement of customer satisfaction
IS/ISO 19011 : 2002	Guidelines for quality and/or environmental management systems auditing

ANNEX C

(*Clause* 4.1)

TYPICAL PROCESS FOR FINALIZING ENGINEERING FEASIBILITY REPORT

FLOW CHART



INPUTS

- Ultimate capacity of the project
- Units to be installed in the current phase
- Unit rating
- Source of water, water availability and water quality
- Fuel (main as well as alternate) and its source
- Vicinity plan
- Other site specific data
- Environmental conditions, if available

PROCESS

- Nomination of discipline coordinator by respective Head of Department.
- The coordinator to list out the chapters plan of the FR and circulate to all the discipline coordinators.
- The coordinator to identify the various inputs along with the source required from other groups and obtain the same. Compile the Bill of Quantities and the description of main plant auxiliaries, plants switchyard, water and fuel requirements, after receipt from various groups.

RESOURCES

- Nomination of overall coordinator
- Computer facilities for Layout drawings
- Reprographic facilities

OUTPUT

Feasibility Report Document approved by Head of Department to be forwarded to Projects Group in two hard copies and one soft copy.

CONTROL

- Review of the FR and BOQ by the Group Head.
- Review and approval of the combined document by the General Manager.
- Time Schedule as requested in inputs.

RECORD

Overall coordinator to maintain record of reviews and approvals.

ANNEX D

(*Clause* 8.2.2)

EXAMPLES OF INTERNAL QUALITY AUDIT

The efficacy of the quality management system depends on internal quality audits. Quality assurance department or any other designated department should have the responsibility to plan and execute the internal quality audits. The department should also monitor the corrective action taken based on nonconformities noticed during the audits and prepare a summary of audit results for review by the management.

The audit can be viewed as a process which itself must be adequately documented and controlled against established criteria. This is accomplished by establishing a procedure for internal quality audits. The audit process consists of determining as to whether a system exists, whether the system is implemented and to make a judgment on its effectiveness. By questioning, witnessing the activities, and collecting objective evidence, the auditor can assess the adequacy of the system and its compliance.

Development of Audit Plan

The approach to internal quality audits must be systematic. Internal quality audit should be conducted according to a pre-planned schedule so that each applicable requirement of IS/ISO 9001 is addressed and all areas of the organization are covered within a stipulated period. The audit planning commences with the development of an audit programme, covering all the departments/functions affecting quality. The period of auditing should be determined in advance. A typical specimen is contained in Annex E. The frequency of audit will depend on several factors including the criticality of the functions being audited. There must be a provision to adjust the frequency of audits based on the results obtained. In the early stages of implementation of quality systems, it will generally be necessary to carry out the audits more frequently to ensure that the implementation of quality system has been effective.

Scheduling of Audit Activities

If a programme is available as described in Annex F, firm schedules for the forthcoming two or three months may be prepared by the department responsible for audits. The sequence of activities to be performed during the audit or the scope need not be specified on the schedule. The schedule may contain the following information and distributed to the departments/functions concerned:

a) Audited activity (from annual schedule).
b) Date of commencement of audit and likely duration.
c) Audit team leader and members.

These schedules may be modified to suit circumstances, as long as all planned audits are performed within the stipulated quarter.

Qualities of the Auditors

The satisfactory and practical administration of an audit depends to a great extent on the personnel carrying out the audits. The auditor's role is not merely to report facts, but to be able to obtain information from a variety of sources and interpret the data to make a judgment as to the effectiveness of the quality system. As such, a good auditor may require the following attributes:

a) Professional competence,
b) Integrity,
c) Objectivity,
d) Persistence,
e) Flexibility,
f) Tact,
g) Adaptability,
h) Curiosity,
j) Common sense,
k) Consistency, and
m) Leadership.

The auditor is required to interact with individuals at all operational and managerial levels. Therefore his personal skills assume importance.

Selection of Audit Team

The selection of audit team comprising a lead auditor and members is important for effective auditing. If the organization does not have qualified personnel it may use external sources to perform the audits. The techniques of auditing can be acquired by training and practice and the organization can, in due course, develop suitable personnel for carrying out audits.

Carrying Out the Audit

Each audit begins with a brief opening meeting between the audit team, and the head of the department of the area to be audited. During this meeting, the auditor discusses the approach, the scope of audit and any administrative arrangements. In carrying out audit, the auditor should be accompanied by a representative of the area concerned.

To facilitate effective conduct of audit, the auditor may prepare checklists for guidance and follow the audit trail as it opens up, to collect objective evidence of any non-compliance or deficiency in the system. The results of this examination should be recorded on the checklist pages or on supplemental notes.

On completion of the audit, a closing meeting is held by the auditor(s) with the management of the area/department concerned. At this meeting, the findings (nonconformities) or observations are discussed. The possible corrective action to be taken, and time required for corrective action are also discussed. Copy of the nonconformity report or audit findings along with conclusions, are provided to the management/auditee at the closing meeting. The audit findings should be presented as a statement giving details such as nonconformities observed, where they were observed, and why they were nonconformities. Cross-reference to the clause of IS/ISO 9001 or manual or document, should be given invariably. This will assist the management/ department concerned in taking corrective action. The audit report is prepared after the closing meeting by the audit team leader and forwarded to the designated person in charge of audits. The audit report normally contains the following information:

a) Audit title, number and other identifying information;
b) Background information, such as, audit purpose, scope, dates, audit team members, and procedures used. A brief description of the activities audited;
c) Summary of any findings or observations and how they affect the products and/or services or deliverables and overall conclusions of the effectiveness of the quality programme as implemented by the audited department(s);
d) Listing of those who participated in the audit. This is normally presented as an attachment; and
e) Specific findings (nonconformities) or observations as attachments.

The auditee department should be provided with the report by management representative and should be requested for corrective action as applicable. A response to audit findings and the corrective action taken is to be submitted by the Auditee Department normally within 30 days of audit closing meeting.

In many organizations, the nonconformity audit report and corrective action response are all combined in single format and copies are distributed to all affected. A typical format is given in Annex G.

Follow-up

The audit team leader or the designated department for Audits should follow up the corrective action taken by the auditee through:

a) Obtaining a written response to the audit report.
b) Evaluating the adequacy of the response.
c) Verifying that corrective action has been accomplished as scheduled.
d) Determining that the action was effective in preventing recurrence.

Follow up action may be accomplished through written communication, review of revised documents, re-audit after the reported implementation date. The audit team leader or designated person of audits, should periodically review the status of outstanding corrective action and take steps to resolve outstanding audit issues.

Summary results of the reports of quality audits should be circulated to the senior management of the organization on regular basis (may be quarterly or annually) to appraise them of the effectiveness of the quality system. This will form a significant input into the management review of the quality system. The summary can highlight the requirements which cause frequent non-compliances; areas, activities or processes which are frequently not complying, and the corrective action recommended and taken in these areas.

Records

The following audit records are to be maintained by the Audit Team Leader and designated department of Audit Programmes:

a) Audit notification memo and Audit Plan;
b) Blank audit checklists used;
c) Audit report and forwarding memo; and
d) Audit response, including completed audit finding response forms.

The following working records may also be maintained:

a) Auditor/Lead Auditor qualification records,
b) Completed audit check lists and auditor's working papers,
c) Related miscellaneous correspondence,
d) Annual audit programmes and any revisions,
e) Quarterly audit schedules, and
f) Auditing procedures used.

The duration of keeping these records is to be decided, as also the storage and retrieval methods.

Check list

a) Has the organization assigned the responsibility to a designated person for carrying out internal quality audits?
b) Has a programme for audits been established covering all departments and activities of the organization?
c) How is this programme developed and documented?
d) Have the criticality of activities is taken into account in determining the frequency of audits?
e) Are detailed procedures available for the conduct of audit?
f) Are checklists prepared for use in audits?
g) Has the criteria for auditors qualification been established?
h) Are formats available for Audit Schedule and Audit Plans?
j) Do the audit reports identify the activity, the area, the date and the findings of the audit?
k) What is the method used for taking up the reports of audits and non-compliances, with the department concerned?
m) What is the provision made for the management of the area audited to detail corrective action to be taken, the timescale for action and who is responsible?
n) How are corrective action followed up?
p) How are audit results made available for use in management review?
q) What are the various records used for internal quality audits?

Example of Internal Audit Procedure

1. Purpose

To define the process for conducting periodic audits of the quality management system. The procedures defines the process for scheduling, conducting and reporting of quality management system audits.

2. Scope

This procedure applies to all internal quality management system audits conducted at the site.

3. General

Internal audits help to ensure the proper implementation and maintenance of the quality management system by verifying that activities conform to documented procedures and that corrective action are undertaken and are effective.

All audits are conducted by trained auditors. Records of auditor training are maintained in accordance with Training Procedure.

The Management Representative (MR) is responsible for maintaining audit records, including a list of trained auditors, auditor training records, audit schedules and audit reports.

Audits are scheduled to ensure that all quality management system requirements and all functions are audited at least once each year. Additional audits can be conducted keeping in view the following:

a) Importance of the processes (for example customer related processes).
b) Status of the process (for example, changes in the process steps, process capability changes, increase of customer complaints etc).
c) If results of previous audit indicate larger nonconformities in a process or department.

Management Representatives (MR) informs all the areas and functions subject to the auditors prior to the audit. (*see* Annex E for Audit Programme Format and Annex F for Audit Schedule Format).

4. Procedure

Audit Team Selection — One or more auditors comprise an audit team. When the audit team consists of more than one auditor, a Lead Auditor will be designated. The Lead Auditor is responsible for audit team orientation, coordinating the preparation of the audit report.

Audit Team Orientation — The Lead Auditor will assure that the team is adequately prepared to initiate the audit. Pertinent policies, procedures, standards, regulatory requirements and previous audit reports are made available for review by the audit team.

Written Audit Plan — The Lead Auditor is responsible for ensuring the preparation of a written plan for the audit. Audit checklist are prepared and used as a guide for this plan.

Conducting the Audit

a) A pre-audit briefing meeting is held with in-charge of the department to be audited to review the scope, plan and schedule for the audit.
b) Objective evidence is examined to verify conformance to quality management system requirements, including procedures, process documents, work instructions, etc. All audit findings are documented.
c) Specific attention is given to verify corrective action on the audit findings from previous audits.
d) A post-audit briefing meeting is held to present audit findings, clarify any misunderstanding and summarize the audit results.

Reporting Audit Results

a) The team Leader prepares the audit report, which summarizes the audit scope, identifies the audit team, describes sources of evidence used and summarizes the audit results.
b) Findings requiring corrective action are entered into the corrective action forms (*see* Annex E for the format).

Audit Report Distribution

a) The MR is responsible for communicating the audit results to responsible area and/or functional management.
b) Management in the affected areas and/or functions are responsible for any flow-up actions needed as a result of the audit.

Audit Follow-up — The MR is responsible for tracking the completion and verification of corrective action.

Record Keeping — Audit reports are retained for at least two years from the date of audit completion. The MR is responsible for maintaining such records.

ANNEX E

(*Clause* 8.2.2 and *Annex* D)

INTERNAL QUALITY AUDIT PROGRAMME

Sl No.	Department	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
1.	Top Mgmt												
2.	MR Office												
3.	Marketing												
4.	Design												
5.	Purchase												
6.	Production-I												
7.	Production-II												
8.	Stores												
9.	Maintenance												
10.	Q. Assurance												
11.	Training												
	—												
	—												

ANNEX F

(*Annex* D)

TYPICAL INTERNAL AUDIT SCHEDULE

Period:				
Department to be Audited	Auditee Responsible	Audit Scope/Activity	Dates of Audit Coverage	Auditor's Name
Circulated to:				
				Sd/- Management Rep.

ANNEX G

(*Annex* D)

NONCONFORMITY AUDIT AND CORRECTIVE ACTION REPORT

Name of the Company		Ref No.
Audit Ref No.	Department/Location	Date
Document used for evaluation		
Details of Nonconformity:		
Signature of Auditor	Representative of Auditee	
Comments/Recommendation/Agreed Action:		
Audit findings acknowledged by	Name/Title	Response required by (Date)
Corrective action taken:		
Proposed completion date	Corrections taken	Date ....
Corrective action verified with comments		Yes/No
Verified by	Date	
NCR Closed	Signature	Date ....

ANNEX H

(*Clause* 8.4)

STATISTICAL TECHNIQUES
MATRIX SHOWING APPLICATION OF VARIOUS STATISTICAL TECHNIQUES IN CERTAIN FUNCTIONAL AREAS

Functional Areas Statistical Techniques	Product/ Service/ Process Design	Process Control/ Noncon-formity Avoidance	Problem Analysis/ Finding Root Causes	Risk Determi-nation	Finding Root Causes	Establish-ment of Product/ Process Limits	Fore-casting	Verifica-tion	Measure-ment of Quality Charac-teristics
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Control Chart techniques [IS 397 (Parts 0 to 4)]		*					*		
Sampling Inspection [IS 1548, IS 2500 (Part 1 and 2) and IS 4905]				*				*	*
Sampling Size Determination			*						
Precision of Test Methods [IS 15393/ISO 5725]						*			*
Tests of Significance [IS 6200 (Parts 1 to 4)]			*					*	
Summarization of Data [IS 7200 (Parts 1 and 2)			*						
Scatter Diagram Correlation Regression Analysis [IS 7300]	*				*		*		
Analysis of Variance [IS 7300]	*						*		
Probability Distributions [IS 9300]				*		*			
Design of Experiments [IS 10427]	*						*		
Process Capability [IS 10645]	*	*				*			
Analysis of Means [IS 12347]						*		*	
Pareto Diagram and Cause and Effect Diagram [IS 15431]		*	*	*	*				

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